SUPPLEMENTARY TABLE 1
REASONABLE CHARGES DATA SOURCES — v3.18

	Paragraph	Subject	Data Source	Edition
DME	(f)(5)(ii)	GAAFs	Medicare SAF 5% Sample, Part B component	CY 2013
Dent	(h)(3)	GAAFs	Milliman, Inc., Dental Health Cost Guidelines	CY 2015
Opt	(e)(4)	GAAFs	Milliman, Inc., Health Cost Guidelines, Population Assumptions	CY 2015
DME	(f)(5)(iii)	charges, weighted average, nationwide	Milliman, Inc., Health Cost Guidelines, Population Assumptions	CY 2015
Anes	(g)(3)(ii)	conversion factor GAAFs	Milliman, Inc., Health Cost Guidelines, Population Assumptions	CY 2015
Phys	(f)(3)(i)	conversion factor, nationwide	Milliman, Inc., Health Cost Guidelines, Population Assumptions	CY 2015
Phys	(f)(3)(iii)	conversion factor GAAFs	Milliman, Inc., Health Cost Guidelines, Population Assumptions	CY 2015
Anes	(g)(3)(i)	conversion factor, nationwide	Milliman, Inc., Health Cost Guidelines, Population Assumptions	CY 2015
Dent	(h)(2)	charges, 80th percentile, nationwide	Milliman, Inc., Health Cost Guidelines, Population Assumptions	CY 2015
Dent	(h)(3)	GAAFs	Milliman, Inc., Health Cost Guidelines, Population Assumptions	CY 2015
Lab	(i)(3)(i)	conversion factor, nationwide	Milliman, Inc., Health Cost Guidelines, Population Assumptions	CY 2015
Lab	(i)(3)(iii)	conversion factor GAAFs	Milliman, Inc., Health Cost Guidelines, Population Assumptions	CY 2015
DME	(f)(5)(ii)	GAAFs	Milliman, Inc., Health Cost Guidelines, Population Assumptions	CY 2015
Dent	(h)(2)	charges, 80th percentile, nationwide	National Dental Advisory Service nationwide pricing index	CY 2015
Dent	(h)(2)(ii)	charges, 80th percentile, nationwide, for unlisted procedures	National Dental Advisory Service nationwide pricing index	CY 2015
INPT	(b)(3)	GAAFs	VA nationwide admits by DRG code	FY 2014
DME	(f)(3)	charges for codes with no RVUs	VA nationwide distribution of items and charges	FY 2014
Anes	(g)(2)	RVUs for unlisted procedures	VA nationwide distribution of procedures and services	FY 2014
Lab	(i)(2)(ii)	RVUs, unlisted procedures	VA nationwide distribution of procedures and services	FY 2014
Phys	(f)(2)(iii)	RVUs, unlisted procedures	VA nationwide distribution of procedures and services	FY 2014
Dent	(h)(2)(ii)	charges, 80th percentile, nationwide, for unlisted procedures	VA nationwide distribution of procedures, services, items, and supplies	FY 2014
DME	(f)(4)	charges for unlisted procedures	VA nationwide distribution of procedures, services, items, and supplies	FY 2014
Opt	(e)(3)(ii)	80th percentile charges, codes with no APC	VA Reasonable Charges - Table F	CY 2015
Phys	(f)(2)(ii)	RVUs, codes with no Medicare RVUs	VA Reasonable Charges - Table G	CY 2015
Dent	(h)(2)	charges, 80th percentile, nationwide	VA Reasonable Charges - Table I	CY 2015
Lab	(i)(2)(ii)	RVUs, codes with no Medicare-based RVUs	VA Reasonable Charges - Table J	CY 2015
DME	(f)(3)	charges for codes with no RVUs	VA Reasonable Charges - Table K	CY 2015
Phys	(f)(3)(iii)	GAAFs	VA Reasonable Charges - Table L	CY 2015
INPT	(b)(3)	GAAFs	VA Reasonable Charges - Table N	CY 2015
SNF	(c)(3)	GAAFs	VA Reasonable Charges - Table O	CY 2015
Opt	(e)(4)	GAAFs	VA Reasonable Charges - Table P	CY 2015
DME	(f)(5)(ii)	GAAFs	VA Reasonable Charges - Table Q	CY 2015
Dent	(h)(3)	GAAFs	VA Reasonable Charges - Table R	CY 2015

SUPPLEMENTARY TABLE 1
REASONABLE CHARGES DATA SOURCES — v3.18

Charge Type Abbreviations	Abbreviations
Amb = Ambulance and Other Emergency Transportation Charges Anes = Professional Anesthesia Units Dent = Outpatient Dental Professional Charges DME = Durable Medical Equipment, Supplies, Vision and Hearing Hardware Charges INPT = Acute Inpatient Facility Charges Lab = Pathology and Laboratory Services Relative Value Units Obs = Observation Care Facility Charges Opt = Outpatient Facility Charges PH = Partial Hospitalization Charges Phys = Physician and Other Professional Services Relative Value Units SNF = Skilled Nursing Facility / Sub-Acute Inpatient Facility Charges	APC = Ambulatory Payment Classification CMS = Centers for Medicare and Medicaid Services CPI-U = Consumer Price Index - All Urban Consumers DME = Durable Medical Equipment DRG = Diagnosis Related Group GAAF = Geographic Area Adjustment Factor HCPCS = Healthcare Common Procedure Coding System MDR = Medical Data Research MedPAR = Medicare Provider Analysis and Review OPPS = Outpatient Prospective Payment System RBRVS = Resource-Based Relative Value Scale RVU = Relative Value Unit SAF = Standard Analytical File VA = Department of Veterans Affairs

SUPPLEMENTARY TABLE 2

REASONABLE CHARGES DATA SOURCES — v3.18 — WHERE TO OBTAIN

Database	Where To Obtain
CMS anesthesia base units	CMS Internet site, http://www.cms.gov/
CMS Medicare Provider Analysis and Review (MedPAR) Record	CMS Internet site, http://www.cms.gov/
CMS Medicare Provider Analysis and Review (MedPAR) Record - SNF File	CMS Internet site, http://www.cms.gov/
CMS Provider of Services Listing	CMS Internet site, http://www.cms.gov/
CPI-U, various components, seasonally adjusted	Bureau of Labor Statistics Internet site, CPI section, http://www.bls.gov/cpi/
Essential RBRVS	Optum, 2525 Lake Park Blvd., Salt Lake City, UT 84120
FAIR Health databses	FAIR Health site, http://www.fairhealthus.org
MarketScan Claims Database	Truven site, https://marketscan.truvenhealth.com
Medicare APC payment amount	CMS Internet site, http://www.cms.gov/
Medicare Clinical Diagnostic Laboratory Fee Schedule	CMS Internet site, http://www.cms.gov/
Medicare conversion factor	CMS Internet site, http://www.cms.gov/
Medicare DME Fee Schedule	CMS Internet site, http://www.cms.gov/
Medicare Geographic Practice Cost Index, practice expense	CMS Internet site, http://www.cms.gov/
Medicare Geographic Practice Cost Index, work expense	CMS Internet site, http://www.cms.gov/
Medicare Parenteral and Enteral Nutrition Fee Schedule	(Included as part of DME Fee Schedule download)
Medicare Physician Fee Schedule payment levels	CMS Internet site, http://www.cms.gov/
Medicare Physician Fee Schedule RVUs, practice expense	CMS Internet site, http://www.cms.gov/
Medicare Physician Fee Schedule RVUs, work expense	CMS Internet site, http://www.cms.gov/
Medicare SAF 5% Sample, DME component	CMS Internet site, http://www.cms.gov/
Medicare SAF 5% Sample, outpatient facility component	CMS Internet site, http://www.cms.gov/
Medicare SAF 5% Sample, Part B component	CMS Internet site, http://www.cms.gov/
Milliman, Inc., Dental Health Cost Guidelines	Milliman, Inc., 1301 5th Ave. Suite 3800, Seattle, WA 98101-2605
Milliman, Inc., Health Cost Guidelines	Milliman, Inc., 1301 5th Ave. Suite 3800, Seattle, WA 98101-2605
Milliman, Inc., Health Cost Guidelines, Population Assumptions	Milliman, Inc., 1301 5th Ave. Suite 3800, Seattle, WA 98101-2605
National Dental Advisory Service nationwide pricing index	Wasserman Medical Publishers, P.O. Box 510949 Milwaukee, WI 53203
VA nationwide admits by DRG code	Veterans Health Administration
VA nationwide distribution of procedures, services, items, and supplies	Veterans Health Administration
VA Reasonable Charges tables	US Department of Veterans Affairs, http://www1.va.gov/

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- The Healthcare Cost Report Information System (HCRIS) dataset contains cost, statistical, financial and other information from the Medicare Hospital Cost Reports submitted for Medicare Certified Hospitals.
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PLAINTIFF'S EXHIBIT 80

SPINAL CORD STIMULATION VERSUS REOPERATION FOR FAILED BACK SURGERY SYNDROME: A COST EFFECTIVENESS AND COST UTILITY ANALYSIS BASED ON A RANDOMIZED, CONTROLLED TRIAL

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OBJECTIVE: We analyzed the cost-effectiveness and cost-utility of treating failed back surgery syndrome using spinal cord stimulation (SCS) versus reoperation.

MATERIALS AND METHODS: A disinterested third party collected charge data for the first 42 patients in a randomized controlled crossover trial. We computed the difference in cost with regard to success (cost-effectiveness) and mean quality-adjusted life years (cost-utility). We analyzed the patient-charge data with respect to intention-to-treat costs and outcomes as a randomized group, treated as intended (costs as randomized, crossover failure assigned to a randomized group), and final treatment costs and outcomes.

RESULTS: By our mean 3.1-year follow-up, 13 of 21 patients (62%) crossed from reoperation versus 5 of 19 (26%) from SCS ($P < 0.025$). The mean cost per success was US $117,901 for crossovers to SCS. No crossovers to reoperation achieved success despite a mean per-patient expenditure of US $260,584. The mean per-patient costs were US $31,530 for SCS versus US $38,160 for reoperation (intention to treat), US $48,357 for SCS versus US $105,928 for reoperation (treated as intended), and US $34,371 for SCS versus US $36,341 for reoperation (final treatment). SCS was dominant (more effective and less expensive) in the incremental cost-effectiveness ratios and incremental cost-utility ratios. A bootstrapped simulation for incremental costs and quality-adjusted life years confirmed SCS's dominance, with approximately 72% of the cost results occurring below US policymakers' "maximum willingness to pay" threshold.

CONCLUSION: SCS was less expensive and more effective than reoperation in selected failed back surgery syndrome patients, and should be the initial therapy of choice. SCS is most cost-effective when patients forego repeat operation. Should SCS fail, reoperation is unlikely to succeed.

KEY WORDS: Cost effectiveness, Cost utility, Failed back surgery syndrome, Repeat operation, Spinal cord stimulation

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Failed back surgery syndrome (FBSS) is a major public health problem, affecting an estimated 5 to 40% (12, 18, 26) of patients undergoing surgical treatment for back pain in the United States. From 1991 to 2002, the number of surgical procedures on the spine has increased from approximately 200,000 to approximately 1 million (8, 30). Management of FBSS is a costly (9, 27) challenge for practitioners of multidisciplinary pain management as well as for clinicians who offer medical, surgical, or behavioral therapy.

Spinal cord stimulation (SCS) and reoperation are accepted treatments for FBSS. Compared with reoperation, SCS has the advantages of being reversible, minimally invasive, and associated with lower morbidity. In addition, a preimplantation screening trial of SCS is possible and routine. In our experience with carefully selected FBSS patients, SCS provides better results than reoperation in terms of pain management, neurological functioning, quality of life, and the ability of patients to remain employed (20, 23, 24, 25).

Because implanted stimulation devices are relatively expensive, analysis of the cost-effectiveness and cost utility of treating FBSS with SCS versus reoperation provides important information for clinicians and third-party payers. We present

such an analysis based on data from our randomized, controlled trial (RCT), which compared the clinical outcome of these treatments for FBSS (21, 22).

PATIENTS AND METHODS

Patients

The first 42 FBSS patients out of 50 enrolled in our RCT of SCS versus reoperation were eligible for the collection of economic data (21, 22). As reported, all study subjects had FBSS characterized by surgically remediable nerve root compression and radicular pain that was refractory to conservative care. We excluded patients with a disabling neurological deficit, radiographically demonstrated critical cauda equina compression or gross instability necessitating fusion, significant untreated dependency on prescription narcotic analgesics or benzodiazepines, major untreated psychiatric comorbidity, unresolved issues of secondary gain, a concurrent clinically significant or disabling chronic pain problem, or a complaint of axial (low back) pain exceeding radicular pain.

The RCT protocol (*Fig. 1*) modeled clinical practice by allowing patients randomized to one therapy to cross to the other therapy upon request. For patients randomized to reoperation, the earliest crossover point was 6 months after reoperation. Patients randomized to SCS who failed the screening trial could cross immediately.

Economic Analysis

Our analyses of the economic data are reported in accord with the *Spine* guidelines for economic evaluations to the extent applicable (15). We measured the cost of healthcare resource use from the perspective of the health services provided in a hospital for each patient from the time of randomization.

The Johns Hopkins Hospital billing department provided data on hospitalization-related costs, including admission; room and board; operating room; pharmacy; radiology; laboratory; medical and surgical supplies; physical, occupational, and respiratory therapy; and other charges (i.e., anesthesia, blood, etc.). We gathered professional charge data directly from the pertinent departments and from the Johns Hopkins Pain Treatment Center. The costs were incurred and are reported in 1991 to 1995 United States dollars.

An unbiased third-party medical billing specialist eliminated data not pertinent to the treatment of FBSS. Other direct healthcare costs such as family physician consultations and patient direct (e.g., travel) and indirect (e.g., those due to loss of employment) costs are not reported here.

The first endpoint we reported for our RCT was frequency of crossover, which indicated failure of the randomized treatment (22). When long-term follow-up was complete, we reported our secondary measures of success (at least 50% pain relief and patient satisfaction with treatment) (21). An impartial third party collected clinical baseline and outcome data.

A cost-effectiveness analysis compares two or more interventions in terms of costs and effects, with the result expressed as the incremental cost per additional patient success (15). We analyzed cost effectiveness by dividing the difference in the SCS and reoperation per patient cost by the difference in the proportion of patients achieving a successful outcome for each procedure.

A cost-utility analysis is a particular method used to conduct a cost-effectiveness analysis; its result is typically expressed in terms of life expectancy adjusted by the quality (or "utility") of the patient's state of health. Thus, the outcome of a cost-utility analysis is "cost per quality-adjusted-life-year (QALY)" (15). Based on the method used by Muller et al. (17) and described in a SCS cost effectiveness analysis by Taylor and

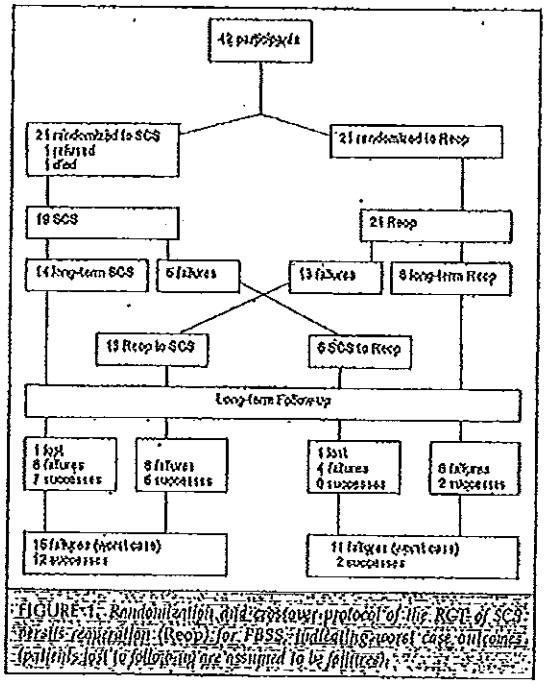

FIGURE 1. Randomization and crossover protocol of the RCT of SCS versus reoperation (Reop) for FBSS, indicating worst case outcomes (patients lost to follow-up are assumed to be failures).

Taylor (28), we imputed a utility of 0.59 to equal treatment failure and 0.83 to equal treatment success (a utility of 1.0 would indicate perfect health and a score of 0 would indicate death) (15). We assumed that patients attained a utility score at the crossover point (the rate of crossover was a primary outcome of the RCT) and at the end of the follow-up period. Based on the premise of no group survival advantage, we calculated the incremental QALY by integrating the time each patient spent within a particular utility from randomization to the time of the last follow-up evaluation. We then divided the difference in the SCS and reoperation per patient cost by the difference in the mean QALY for each procedure.

Three forms of analysis are presented: 1) intention to treat (all costs and outcomes assigned to a randomized group), 2) treated as intended (all costs and outcomes assigned to randomized group with crossover considered a failure), and 3) final treatment (all costs and outcomes, including crossover outcomes, assigned to final treatment instead of a randomized group).

Differences among the groups in terms of success, QALY gain, and costs were compared using either a χ^2 test or Student's t test. Confidence intervals (95%) for mean differences were calculated using bias-corrected non-parametric bootstrapping (outcome statistics calculated for 1000 randomly derived samples drawn from and the same size as the parent population; the samples are assumed to reflect the parent population accurately). The bootstrapped cost-effectiveness (cost-QALY) pairs were graphically represented on a cost-effectiveness plane. (A cost-effectiveness plane shows individual pairs of incremental cost and effect values and indicates the probability that a therapy is cost effective. For an explanation of the rationale behind the use of cost effectiveness planes, see [11]). All analyses were conducted using Stata software (version 8; Stata Corp., College Station, TX).

RESULTS

All but one of the 42 patients consented to the collection of cost data from third-party payers and outside healthcare providers. Another patient, who was an initial SCS success, died of unrelated causes (myocardial infarction) before completing follow-up and was censored because of incomplete cost and outcome data. Thus, this analysis includes data from 40 patients (19 men and 21 women; age range, 31–76 yr; mean age, 53 yr). As *Table 1* illustrates, no statistically significant difference was observed in demographic characteristics between SCS and reoperation patients. The mean follow-up period was 3.1 years (range, 1.6–4.7).

A total of 26 patients (21 as randomized and five crossovers) had one or more of 30 reoperations, including 11 laminoforaminotomy (one with fusion), 13 laminectomy (three with fusion), three fusion, two discectomy, and one discectomy and fusion.

Twenty-nine patients received a total of 32 implanted stimulators (17 as randomized, 12 as crossover, and 3 replacements). Of the 19 patients randomized to SCS, two received only temporary stimulators, three had their systems removed, two had removal/replacements, and one had a revision. Of 13 reoperation patients who crossed to SCS, one received only a temporary stimulator and one had a removal/replacement. Two patients, one from each randomized group, were hospitalized at the Johns Hopkins Pain Treatment Center.

Clinical Outcome

Most of the patients randomized to reoperation (13 out of 21; 62%) crossed over to SCS. Of the patients randomized to SCS, five out of 19 (26%) crossed over to reoperation (*Fig. 1*). The difference in the rate of crossover favoring SCS was statistically significant ($P < 0.025$).

It was possible to obtain long-term clinical data for 38 of the 40 patients (*Fig. 1*). The two patients lost to follow-up were participants randomized to SCS, one of whom had crossed over to reoperation. Among the patients available for long-term follow-up, seven out of 17 (41%) randomized to SCS versus two out of 21 (10.5%) randomized to reoperation reported success from their randomized treatment ($P < 0.025$). Counting both losses as failures (worst case analysis), seven out of 19 (37%) randomized to SCS (all with SCS) and seven out of 21 (33%) randomized to reoperation (two with reoperation, five after crossing over to SCS) reported success from randomized or crossover treatment. Long-term crossover treatment success was achieved in zero out of four patients who crossed over to reoperation and five out of 13 (38%) for the patients who crossed over to SCS.

Cost Effectiveness

As an initial intervention, the mean cost of SCS was $1,778 more than that of reoperation. As a crossover intervention, however, the mean cost of SCS was $3,307 less than that of reoperation. Thus, the mean cost of randomization to SCS was $31,530 versus $38,160 for reoperation, which is a nonsignificant $6,629 differential favoring SCS (*Table 2*).

The cost per patient who achieved long-term success with SCS alone was $48,357 (seven out of 14). The cost per patient who achieved long-term success with reoperation alone was $105,928 (two out of eight). The cost per patient who achieved long-term success with SCS after crossing from reoperation was $117,901 (five out of 13). None of the five patients who crossed over from SCS to reoperation achieved success despite an expenditure of $260,584 (*Fig. 2*).

In the intention-to-treat analysis, counting five reoperation patients who crossed over to SCS as reoperation successes, the difference in outcome (proportion achieving success and QALYs) was not significant between patients randomized to SCS or reoperation. Patients randomized to SCS did, however, experience a higher percentage of treatment success and more QALYs at a lower cost and achieved economic dominance (*Fig. 3*; *Table 2*).

In the treated-as-intended analysis, the difference favoring the SCS group achieved statistical significance in terms of cost, outcome, and QALYs. Thus, SCS achieved economic dominance (*Fig. 4*; *Table 2*).

TABLE 1. Patient demographics

	As randomized		As final treatment		Total
	SCS	Reoperation	SCS	Reoperation	
No. of patients	19	21	27	13	40
Mean age, yr (SD)	50 (3)	54 (3)	52 (3)	51 (4)	53 (14)
		$P = 0.37$		$P = 0.857$	
No. of men (%)	9 (47)	10 (48)	14 (52)	5 (38)	19 (47.5)
		$P = 0.937$		$P = 0.427$	
Mean no. of previous operations (SD)	2.3 (0.3)	2.3 (0.2)	2.2 (0.2)	2.6 (0.2)	2.3 (0.9)
		$P = 0.900$		$P = 0.156$	
Mean no. receiving Worker's Compensation (%)	5 (26)	9 (43)	11 (41)	3 (23)	14 (35)
		$P = 0.273$		$P = 0.277$	

* SCS, spinal cord stimulation; SD, standard deviation.

TABLE 2. Cost effectiveness and cost utility analyses of spinal cord stimulation versus reoperation[a]

	SCS	Reoperation	Mean difference (95% CI)	Absolute risk reduction	ICER	ICUR
Intention to treat						
No. of patients	19	21				
Mean cost ($)	31,530 (SD, 3,782)	38,160 (SD, 3,932)	−6,629 (−17,754–4,148) $P = 0.234$			
Success (%)	7 (36.8)	7 (33.3)		3.5 (−26.1 to 33) $P = 0.816$	SCS dominant	
Mean QALYs	2.14 (SD, 0.08)	2.10 (SD, 0.07)	0.04 (−0.15–0.24) $P = 0.660$			SCS dominant
Treated as intended (crossover = failure)						
No. of patients	19	21				
Mean cost ($)	31,530 (SD, 3,782)	38,160 (SD, 3,932)	−6,629 (−17,754–4,148) $P = 0.234$			
Success (%)	7 (36.8)	2 (9.5)		27.3 (2.2–52.3) $P = 0.036$	SCS dominant	
Mean QALYs	2.25 (SD, 0.09)	2.09 (SD, 0.10)	0.16 (−0.13–0.45) $P = 0.273$			SCS dominant
Crossover patients						
No. of patients	13	5				
Mean cost ($)	48,240 (SD, 4,506)	42,110 (SD, 9,010)	6,770 (−12,551–26,091) $P = 0.466$			
Success (%)	5 (38.5) (crossed over to SCS)	0 (crossed over to reoperation)		38.5 (12–64) $P = 0.249$	Crossover to SCS dominant	
Mean QALYs	2.11 (0.09)	1.97 (0)	0.25 (−0.56–0.07) $P = 0.115$			Crossover to SCS dominant
Final treatment						
No. of patients	32	33				
Mean cost ($)	34,371 (SD, 3,060)	36,341 (SD, 5,782)	−1,971 (−14,045–10,696) $P = 0.754$			
Success	12 (38)	7 (21)		29 (2–56) $P = 0.07$	SCS dominant	
Mean QALYs	2.18 (SD, 0.06)	2.00 (SD, 0.07)	0.18 (−0.03–0.35) $P = 0.09$			SCS dominant

[a] SCS, spinal cord stimulation; CI, confidence interval; QUALYs, quality adjusted life years; ICER, incremental cost effectiveness ratio (cost/success); ICUR, incremental cost utility ratio (cost/QALY); SD, standard deviation; dominant, more effective and less expensive.

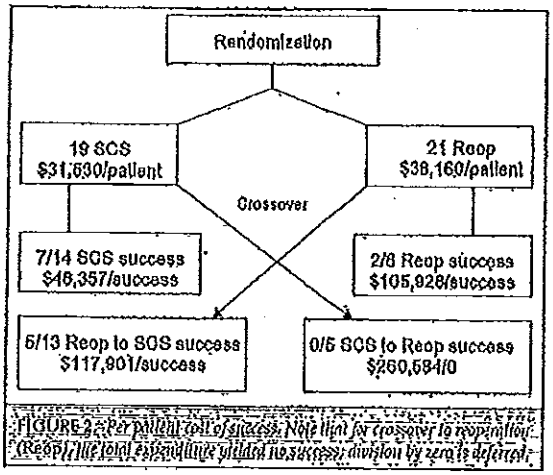

FIGURE 2. Per patient cost of success. Note that for crossover to reoperation (Reop), the total expenditure yielded no success; division by zero is deferred.

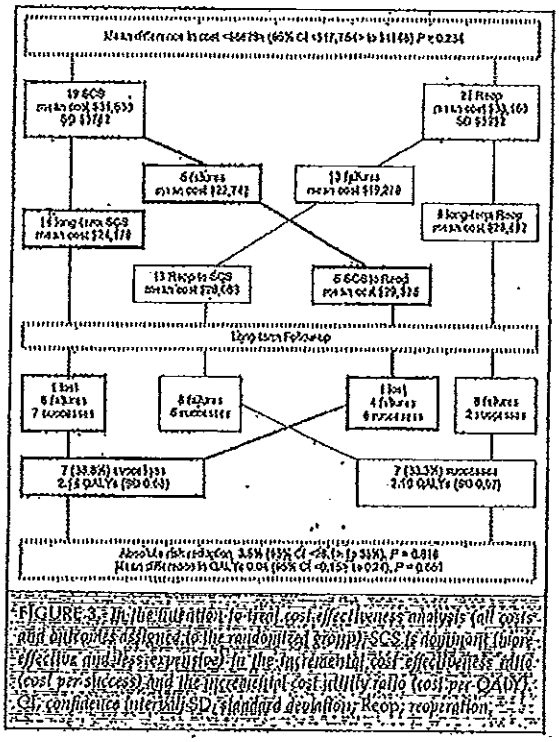

FIGURE 3. In the intention-to-treat cost-effectiveness analysis (all costs and outcomes assigned to the randomized group), SCS is dominant (more effective and less expensive). In the incremental cost-effectiveness ratio (cost per success) and the incremental cost utility ratio (cost per QALY). CI, confidence interval; SD, standard deviation; Reop, reoperation.

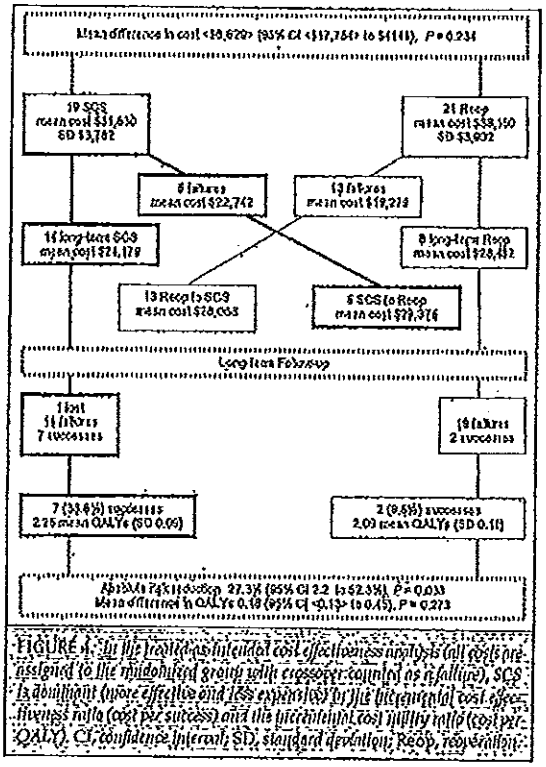

FIGURE 4. In the treated-as-intended cost effectiveness analysis (all costs and outcomes assigned to the randomized group with crossover counted as a failure), SCS is dominant (more effective and less expensive) by the incremental cost-effectiveness ratio (cost per success) and the incremental cost utility ratio (cost per QALY). CI, confidence interval; SD, standard deviation; Reop, reoperation.

In the final treatment analysis, despite the lack of statistically significant difference in overall cost between patients for whom SCS or reoperation was the final treatment, the difference in outcome was statistically significant, with patients for whom SCS was the final treatment experiencing a higher percentage of treatment success and more QALYs at a lower cost; thus, SCS achieved economic dominance (*Fig. 5; Table 2*).

In the intention-to-treat bootstrap simulation for incremental costs and QALYs (*Fig. 6*), 59% of the results fall in the southeast quadrant of the cost effectiveness plane, which confirms the probability that SCS is dominant (less costly and more effective) compared with reoperation. In addition, approximately 72% of the simulation results are below the $40,000 per QALY "maximum willingness to pay" cost effectiveness threshold widely used by health policy makers in the United States (19). Simulations for the treated-as-intended and final treatment analyses (not illustrated) would further emphasize SCS dominance.

DISCUSSION

In 1993, investigators from the Health Technology Assessment Information Service, a branch of the Emergency Care Research Institute, a World Health Organization collaborating center, reported that "SCS appears to be cost-effective versus alternative therapies costing $20,000 per year or more, with 78% or less efficacy" (13). Nevertheless, SCS has a reputation as an expensive therapy; for example, investigators discussing the link between a quality improvement system and health insurance reimburse-

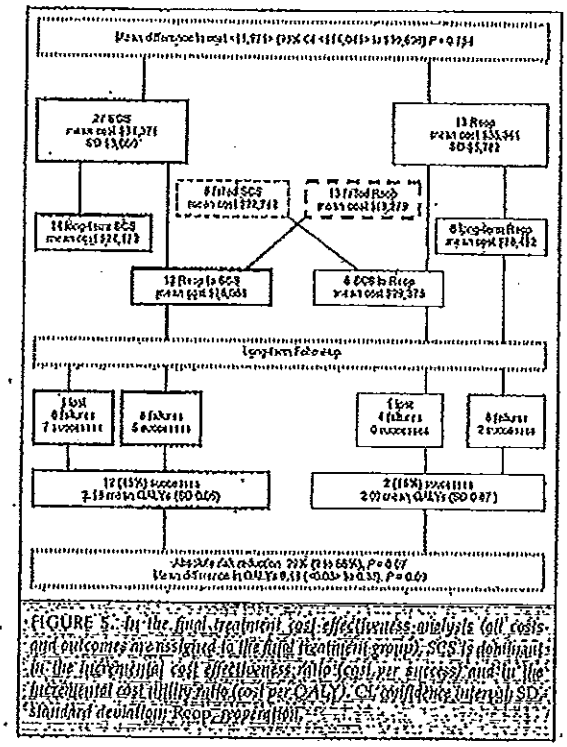

FIGURE 5. In the final treatment cost effectiveness analysis (all costs and outcomes associated to the final treatment group), SCS is dominant in the incremental cost effectiveness ratio (cost per success) and in the incremental cost utility ratio (cost per QALY). CI, confidence interval; SD, standard deviation; Prob, probability.

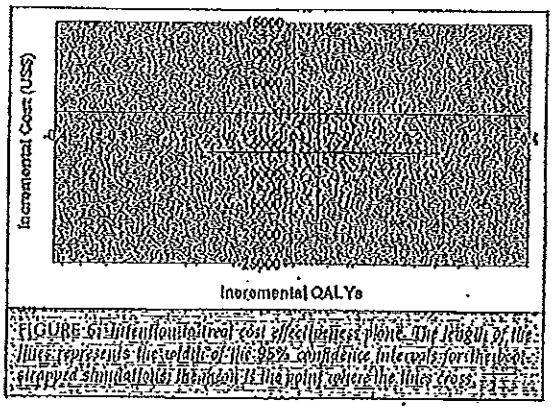

FIGURE 6. Intention to treat cost effectiveness plane. The length of the lines represents the width of the 95% confidence intervals for the bootstrapped simulations in the plane. The point where the lines cross

ment scheme in The Netherlands refer to SCS in the title of their 2005 report as "a high cost medical therapy" (2).

For chronic pain syndromes like FBSS, however, the most expensive therapy is one that offers little clinical benefit to patients, a result of continuing cost accrual for alternative treatments. Despite the fact that implantation of a permanent SCS system is performed only after the patient undergoes a screening trial, the results of SCS treatment are not uniformly positive; thus, long-term follow-up is necessary to determine cost effectiveness.

In 1997, Bell et al. (4) published an economic model of the cost effectiveness of treating FBSS with SCS versus chronic maintenance (including a 10% probability of reoperation). For a 5-year period, the expected per patient cost of SCS was $50,540 versus $76,180 for chronic maintenance. With an SCS success rate of 56%, break-even would occur at 3.5 years for systems with internal power generators that required battery replacement and 2.5 years for those with external power generators.

In their 2004 literature review, Taylor et al. (29) identified four additional FBSS cost effectiveness studies, three cost descriptions with no comparison (3, 7, 10) and a cost analysis using non-interventional therapies as the comparison (16). For that cost analysis, the investigators tracked health care costs in Canadian dollars during a 5-year period in 60 patients who underwent SCS implantation ($29,123/patient) and 44 controls ($38,029/patient). By 2.5 years, the cost of non-interventional therapy exceeded the cost of SCS. Taylor et al. concluded that SCS is cost effective for FBSS, angina, and chronic regional pain syndrome (29).

That same year, French investigators reported the results of a prospective cost-benefit analysis of SCS for FBSS (5). Using data from nine hospitals and 43 patients followed for 24 months, they found that SCS reduced the cost of pain treatment by a mean 64% per patient per year.

The present cost-effectiveness study revealed differences in the mean cost per patient of SCS and reoperation (each including follow-up expenses) depending on whether the therapy was the initial study intervention or a crossover intervention. The mean per patient cost of both SCS and reoperation was less as an initial intervention than as a crossover intervention, and more patients achieved success with SCS as an initial or a crossover therapy.

At a mean $48,857 per success, the cost-efficacy of SCS as a sole therapy was more than twice that of reoperation as a sole therapy (mean, $105,691). This is to be expected considering the fact that 50% (7 out of 14) of the patients treated with SCS alone achieved success versus 25% (2 out of 8) of the patients treated with reoperation alone. The mean cost per patient who achieved long-term success with SCS after crossing over from reoperation was $117,901 (6 out of 13), which is less than half the per patient mean cost of crossing from SCS to reoperation, a move that also failed to result in success for any patient. In addition, were it not for the fact that crossing over to SCS led to a successful outcome for five patients who failed reoperation, the group randomized to reoperation might have incurred even higher health care costs. Although the small absolute differences and wide confidence intervals found in the intention to treat analysis (*Table 2*) resulted in a wide SCS incremental cost effectiveness ratio confidence interval must be interpreted with caution (6). The intention to treat cost effectiveness plane (*Fig. 6*) provides further evidence that SCS is less costly and more effective than reoperation.

Our SCS cost-effectiveness study is the first that approximates real-life medical decision-making because the RCT on

which it is based included crossover to the alternative therapy as a patient right. Conversely, the RCT upon which Kemler and Furnee (14) based their economic evaluation of SCS for "chronic reflex sympathetic dystrophy" did not allow crossover, thus sequestering results in patients randomized to physical therapy alone who ultimately received SCS. The Electrical Stimulation versus Coronary Artery Bypass Surgery in Severe Angina Pectoris Study, which Andrell et al. (1) used for their cost analysis, allowed crossover only in the few cases in which the alternative therapy was indicated for medical or psychological reasons.

In practice, physicians discuss treatment options with their patients. If one treatment fails, the patient is free to pursue the other, either with the original physician or with a new one willing to provide the desired therapy. The importance of offering the most appropriate therapy first is highlighted by the fact that in our study, counting both of our lost subjects as therapeutic losses, patients who crossed over to the other therapy experienced less success with their final therapy than patients who did not cross over; two out of eight patients who did not cross from reoperation were successes versus none of the five who crossed over to reoperation, and seven out of 14 who did not cross over from SCS were successes versus five out of 13 who crossed over to SCS.

Study Limitations

In this comparison of the long-term cost effectiveness of two established treatments for FBSS, we did not consider health care expenditures before entry in this study or patient costs such as transportation after entry. Also, the crossover option built into the RCT permitted and, indeed, required analysis of three subgroups in addition to intention-to-treat: treated-as-intended (did not cross over), crossover treatment only, and final treatment analyses. The sample size for some of these groups was small, and the confidence intervals for costs and outcomes were wide; thus, the study might have been underpowered.

CONCLUSION

Our results indicate that, at a mean follow-up period of 3.1 years, SCS is more cost effective than reoperation in selected FBSS patients and should be the initial therapy of choice. Further study is needed to validate our findings.

Disclosure

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COMMENTS

North et al. have provided clinical information that supports "alternative" surgical strategies in patients with failed back surgery syndrome (FBSS) who would have otherwise undergone conventional decompression or fusion surgery. It is common knowledge that such structural operations are fraught with a low success rate in this patient population. Spinal cord stimulation (SCS) provides an often forgotten alternative. Sometimes it is better to concede structural defeat (i.e., that a structural operation is not likely to help) in favor of a nonstructural alternative (i.e., SCS). North et al. are to be congratulated for reminding all of us of our alternatives, some of which are not that bad in this very difficult to treat patient population.

Edward C. Benzel
Cleveland, Ohio

North et al. present economic data regarding the cost effectiveness and cost utility of SCS in the treatment of patients with FBSS. This data was gathered as part of a randomized controlled crossover trial comparing the clinical effectiveness of SCS with reoperation for selected patients with FBSS. The clinical study was well-conceived and conducted and there is long-term follow-up data of the patient cohort. The clinical outcome showed a decided advantage of SCS over reoperation based on both primary (frequency of crossover from one treatment arm to the other) and secondary (at least 50%) pain relief and patient satisfaction with the treatment.

In spite of the apparent clinical success of SCS reported in the literature and the data presented by the authors, there continues to be concern, particularly among third party payers, that SCS is an expensive and even ineffective therapy. Although it may be true that the initial or upfront costs of SCS may be higher than other therapeutic modalities, it seems fairly clear that over time the economic benefits of SCS become more apparent. Indeed, as early as the point at which patients crossed over in the study, the economic benefits of SCS over reoperation began to emerge. The advantages of SCS over reoperation were even more dramatic when cost per patient who achieved long-term success with either SCS or reoperation alone was compared. Fifty percent of patients achieved long-term success with SCS alone at a cost that was less than 50% of that for patients who achieved success with reoperation alone ($48,357 versus $105,928), a cost savings of nearly $58,000. The cost differential was even more pronounced for patients who achieved long-term success after crossover from SCS or reoperation ($117,901 versus $260,584), representing a cost savings of nearly $143,000. Moreover, despite treatment costs of more than a quarter million dollars, there was not a single patient who crossed from SCS to reoperation who experienced long-term success.

The type of data presented by North et al. represents important information, especially for the future of not only SCS, but also for other types of neuromodulation therapies. It would seem that this type of information is going to become more and more critical for convincing third party payers of the effectiveness of various interventional pain procedures. It would certainly be interesting and perhaps revealing to compare costs of SCS with other conventional nonoperative therapies such as ongoing physical therapy, nerve blocks, and pharmacological management. It would also be interesting to apply this same type of analysis to intrathecal drug delivery. I thank North et al. for providing us with information. I have no doubt that it will prove extremely valuable for those of us who utilize neuromodulation procedures as an integral part of our practice in the management of patients with chronic intractable pain.

Richard K. Osenbach
Durham, North Carolina

After the 2005 study published in this journal, North et al. provide a clear-cut opportunity to discuss patients experiencing FBSS and the possibility of a therapy controlling their pain with a Class 1 study with the neurosurgical community. Although this study is referring to patients with different etiologies of FBSS (laminectomy versus discectomy) and the number of each group is small, the results of the crossover and the final therapeutic results are brilliant.

This article is worthwhile for physicians but is even more important for hospital administrators and health system experts. In countries such as Italy, in which the public health system provides free treatment to all citizens and in which hospital reimbursement is based on the diagnosis-related group system, SCS is considered although it is an expensive treatment and costs more than discectomy or laminectomy. It is an obvious limitation in many health structures to propose that SCS for FBSS patients is the most convenient therapy.

This excellent article provides a clear-cut analysis of the balance between costs and benefits for the health system and emphasizes good results for patients.

The authors should be complimented for this; this article will be of great help in many countries, including mine, in modifying the attitude of the administrators.

Giovanni Broggi
Milan, Italy

North et al. analyzed the cost effectiveness and utility of treating FBSS with SCS or reoperation. Forty-two patients were enrolled in this randomized controlled trial, all of whom had failed lumbar surgery and were characterized by persistent surgically remediable nerve root compression and radicular pain that was refractory to conservative care. The protocol allowed patients randomized to one therapy to crossover to another therapy upon request. For patients randomized to reoperation, the earliest time point at which they could crossover to SCS was 6 months after the reoperation. Patients randomized to SCS who failed the screening trial could crossover to reoperation immediately. The data were analyzed in three manners: intention to treat (all costs and outcomes assigned to a randomized group), treated as intended (all costs and outcomes assigned to the randomized group with crossover considered a failure), and final treatment (all costs and outcomes including crossover outcomes assigned to the final treatment instead of the randomized group). It is a little difficult to follow the flow of the patients through this study, but if one examines the figures carefully, the data becomes clear. The economic outcomes were examined carefully, and the authors concluded that at a mean of more than 3 years of follow-up, SCS was less expensive and more effective than reoperation in these selected patients. It was their recommendation that this be made the initial therapy of choice.

The poor outcomes of patients undergoing surgery for pain syndromes after previous surgery are sobering. Furthermore, it is intriguing that patients with documented nerve root compression fared better

with SCS than decompression. This study presents a unique perspective on the management of FBSS patients; the data presented may be enough to alter many surgeons' practice. It will be interesting to see if the clinical and economic advantages of SCS as a frontline treatment will persist if this approach becomes widespread.

Vincent C. Traynelis
Iowa City, Iowa

As a field, neuromodulation is expanding at an unprecedented pace. By one estimate, the market for neuromodulatory devices will reach $2.0 billion by the end of 2008 (1). The economic impact of this growth has yet to be realized; however, unless these therapies are shown to be cost-effective, their widespread implementation could bring an already overburdened American health care system to a fiscal standstill.

This study by North et al. provides important evidence that SCS, far from being an economic burden, can provide cost savings in the treatment of persistent pain after spinal surgery. As a follow-up to their prospective, randomized study of SCS versus reoperation (2), this group has evaluated cost-effectiveness of SCS in the same cohort of patients. Three different analyses are performed. Intention to treat analysis follows each group (SCS or reoperation) throughout the course of the study, accumulating costs and outcomes regardless of what eventually happens to the patient. Treated as intended follows each group either to a final outcome or to the point of crossover. Patients who crossover are declared treatment failures. Final treatment ignores the path by which each patient arrived at the final treatment group, focusing only on eventual outcome and costs.

Instead of selecting one of these analyses to perform exclusively, the authors have applied all three. In each case, SCS achieved dominance over reoperation in terms of cost per successful outcome. In the intention to treat and treated as intended analyses, SCS was both more effective and less expensive. In five patients who crossed over from SCS to reoperation, no successes were achieved despite an average expenditure of more than $260,000. In the treated as intended analysis, which is probably the most clinically applicable, SCS was less than half as costly as reoperation when expressed as cost per successful outcome.

This is an important study that convincingly demonstrates the cost-effectiveness of SCS when compared with reoperation for the treatment of persistent pain after unsuccessful spine surgery. Future trials of neuromodulation therapies should include similar cost and utility analyses.

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Bullfight by Picasso, 1901. Oil on cardboard mounted on panel. Courtesy of the Stavros S. Niarchos Collection, St. Moritz, Switzerland.

Cost Benefit Analysis of Neurostimulation for Chronic Pain

Nagy A. Mekhail, MD, PhD, Armin Aeschbach, MD, and Michael Stanton-Hicks, MD

Objectives: To assess the healthcare utilization of patients with intractable chronic neuropathic pain treated with spinal cord stimulation and peripheral nerve stimulation and to provide a cost-benefit analysis.

Methods: The case records of 222 consecutive patients who received spinal cord stimulation or peripheral nerve stimulation implants at the Cleveland Clinic Foundation between 1990 and 1998 were reviewed retrospectively. Patients were asked to complete a Neurostimulation Outcome Questionnaire designed to gather data on utilization of healthcare resources starting 1 year before surgical implantation. These data were pooled and net differences in events per patient per year, before and after device implantation were calculated and modeled to 2000 cost data obtained from the Medicare Fee Schedule and Healthcare Financing Administration.

Results: Neurostimulation Outcome Questionnaires were returned by 128 patients. The mean patient age was 46 ± 12.5 years (range 21–71 years) and the mean implant duration was 3.1 ± 2.3 years (range 0.5–8.9 years). The mean per patient total reimbursement of spinal cord stimulation/peripheral nerve stimulation absent pharmacotherapy was $38,187. Patients treated with spinal cord stimulation/peripheral nerve stimulation for pain management achieved reductions in physician office visits, nerve blocks, radiologic imaging, emergency department visits, hospitalizations, and surgical procedures, which translated into a net annual savings of approximately $30,221 and a savings of $93,685 over the 3.1-year implant duration. The large reduction in healthcare utilization following spinal cord stimulation/peripheral nerve stimulation implantation resulted in a net per patient per year cost savings of approximately $17,903.

Discussion: The reduced demand for healthcare resources by patients receiving neurostimulation suggests that peripheral nerve stimulation and spinal cord stimulation treatment, although associated with relatively high initial costs, demonstrates substantial long-term economic benefits. Thus, neurostimulation should be considered as a viable option for the early treatment of patients with intractable chronic neuropathic pain.

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Key Words: cost benefit, neurostimulation, pain, peripheral nerve stimulation, spinal cord stimulation

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Chronic pain adversely affects a significant portion of the adult population in the United States, with approximately 9% of individuals suffering from moderate to severe non-cancer-related chronic pain.[1] Annual economic losses attributed to chronic nonmalignant pain currently exceed 100 billion dollars.[2] Additionally, these cost data underestimate the true economic impact by failing to account for the effect of chronic pain on disability and other social costs, including effects on morbidity and quality of life, lost earnings, and reductions in productivity. Chronic pain accounts for 40 million physician visits per year and 515 million lost work days per year in the United States.[2]

Management of chronic pain often involves frequent physician office visits and analgesic use, emergency department visits and hospitalizations, numerous radiologic imaging studies, multiple corrective surgeries, and interventional pain management procedures. These treatments are generally administered repetitively and at great expense and fail to provide patients with favorable long-term clinical outcomes (ie, reduction in pain and morbidity, improved quality of life). As a consequence, chronic nonmalignant pain represents a significant burden on healthcare resources and alternate interventions are needed.

Neurostimulation of the spinal cord and peripheral nerves has been used for the treatment of intractable chronic neuropathic pain since its first description by Shealy et al in 1967.[3] Several studies have reported that >50% of patients treated with neurostimulation achieve marked improvement in pain relief.[4–12] Additionally, in patients with advanced complex regional pain syndrome, neuroaugmentation led to a 50% reduction in opioid use and quality of life was reported to improve in the majority of treated patients.[13] The benefits of neurostimulation on Visual Analog Scale (VAS) scores and health related quality of life have likewise been reported by Kemler et al.[4] In that study, patients receiving spinal cord stimulation and physical therapy achieved a 2.4-cm decrease in pain VAS scores compared with a 0.2-cm increase in patients receiving only physical therapy. Finally, the majority of

patients treated with neurostimulation state that under similar circumstances they would elect to have the procedure repeated for the same outcome. Nevertheless, although several anecdotal reports have established the short-term efficacy of neurostimulation, the lack of well-controlled, prospective randomized trials continues to limit its wider clinical application, particularly early in clinical pain management strategies. In addition, there is a general lack of data addressing the potential cost benefit of neurostimulation, leading to reluctance on the part of third-party (insurance) payors to reimburse for these procedures.

The utility or value of a procedure is generally determined by the patient through self-reported, subjective assessments of quality of life and symptom (eg, pain) severity.[14] However, reimbursement decisions by third-party payors are often based on objective measures, such as return to work, medication requirement, utilization of the healthcare system, and functional improvement.[15,16] Unfortunately, although third-party payors are interested in reducing costs, their interest is focused primarily on economic medical resource utilization and largely ignores indirect costs to patients, including nonmedical services (eg, family care, home aides), decreased earning capacity and productivity, and intangible costs (eg, associated with suffering and depression). As a result of this approach to reimbursement, the justification for reimbursing neurostimulation treatment requires evidence-based outcome data.[17,18] An important component of evidence-based outcome data is the cost-benefit analysis, including the professional and facility fees accrued in the treatment of the condition and the medical savings realized (ie, patient benefit).[19] Therefore, the objective of this study was to examine the impact of spinal cord stimulation (SCS) and peripheral nerve stimulation (PNS) in patients with intractable chronic neuropathic pain by analyzing the patient utilization of healthcare resources before and after implantation of SCS and PNS systems.

PATIENTS AND METHODS

Patient Selection

Case records from patients who received SCS or PNS implants at The Cleveland Clinic Pain Management Department between 1990 and 1998 were reviewed. Patients had been treated with SCS/PNS implants (Medtronic, Inc., Minneapolis/St. Paul, MN) for a variety of chronic neuropathic conditions, including lower back pain and leg pain after failed back surgery, complex regional pain syndrome (CRPS), neuropathies, and vascular ischemia.

Neurostimulation Outcome Questionnaire

Patients were contacted by mail by a disinterested third party and asked to complete a Neurostimulation Outcomes Questionnaire. Those who acknowledged receiving the questionnaire were contacted by telephone, and nonrespondents were contacted twice by phone. The interviewer was responsible for ensuring that all patients understood the contents and purpose of the questionnaire. The concept of a disinterested third-party interviewer has been well described by North et al.[20]

The Neurostimulation Outcome Questionnaire included questions related to the frequency of utilization of healthcare resources because of pain within a calendar year both before and after implantation of a neurostimulation device. The questionnaire consisted of 57 items that included the number of physician office visits, emergency department visits, hospitalizations, injections, diagnostic tests (ie, magnetic resonance imaging [MRI] and computed tomography [CT] scans), and analgesic use. Although data addressing pharmacotherapy consumption were collected and reported, cost savings data were not analyzed because of the high variability in analgesia use among this patient population and the wide regional variability in pricing. Patients were also requested to include the number of pain-related surgeries they underwent both before and after device implantation.

The net differences in events per patient per year, both before and after implantation of the neurostimulation device, were calculated. Patients whose implanted devices were explanted as a result of malfunction, loss of efficacy, infection, or because of improvement in their conditions were instructed to complete the questionnaire in relation to healthcare utilization as if explantation of the device had not occurred.

Reimbursements—Assessments and Assumptions

The costs of SCS/PNS implants were based on the determination of professional and facility fees.[21,22] Physician fees applicable to 2001 were calculated from *Current Procedural Terminology, Eleventh Edition* (CPT-11) codes assigned to procedures typically performed in this group of patients (Table 1).[22] Costs were based on a national average; no cost indices adjustments were made for regional variations. The following assumptions were made in the calculation of professional fees for the various healthcare utilization categories. Emergency department visits were comprised of a level III visit, with physical examination, laboratory analyses, and radiographic imaging. Professional fees pertaining to hospitalization included those noted for emergency department visits plus an assumption of an average of 3 days duration of stay. Injection nerve blocks were averaged among numerous CPT-11 codes that varied by level of injection. Professional fees for surgery were determined from the average charge for those interventions (ie, laminectomy, sympathectomy, and neuroplasty) typically used in the treatment of lower back pain or CRPS of the upper and lower extremities.[21,22]

Facility costs were determined using *International Classification of Diseases, Ninth Edition/Revision* (ICD-9) codes

TABLE 1. Summary of CPT-11 Reimbursement Codes in Chronic Pain Management

Description	Code
Level III office visit	99213
Emergency department visit	99283
Hospitalization	99219, 99222, 99232
Surgical follow-up	990245
MRI	72141, 72148, 72156
CT scan	72126, 72132
Injection (nerve block)	64470, 64472, 64475, 64476, 64479, 64480, 64483, 64484, 64510, 64520, 27096
Surgery	
Percutaneous implant electrodes	63650
Subcutaneous placement of pulse generator/receiver	63685
Revise/remove neuroreceiver	64595, 63688
Revise/remove neuroelectrode	63660, 64585
Lumbar laminectomy	63012
Sympathectomy, cervicothoracic	64804
Sympathectomy, thoracolumbar	64818
Neuroplasty median nerve at carpal tunnel	64721
Neuroplasty major nerve, arm, or leg	64708

CPT-11, Current Procedural Terminology, Eleventh Edition; MRI, magnetic resonance imaging; CT, computed tomography.

appropriate to each procedure (Table 2).[21] When multiple diagnoses were used to calculate the facility fee, the diagnoses were weighted according to the etiology of the intractable neuropathic pain (Table 3). For instance, we encountered CRPS I upper:lower extremities in a 9:1 ratio and weighted the analysis accordingly. For those procedures requiring hospitalization (eg, 2-stage surgical SCS implant, PNS implant, SCS removal), the average length of hospitalization was determined. Facility costs for outpatient procedures that required extensive intervention (eg, nerve block injection, MRI scan) were calculated from ICD-9 codes. The cost of the SCS/PNS pulse generator (Itrel III®, Medtronic, Inc.) and leads were determined from Medicare reimbursements. The pulse generator and leads are reimbursed at approximately $8,000 and $1,500, respectively. Cost indices for anesthesia (both professional and facility fees) for all surgical procedures were not included because of the high variability in anesthesia unit price, length of procedure, and number of concurrence, which make the data extremely difficult to analyze. Likewise, data addressing potential cost savings in opioid and nonopioid drug utilization were not quantitatively included in the final cost savings analysis due to the high variability in medication utilization (around the clock use with and without breakthrough pain medications) and broad regional price variability. However, to assess the qualitative change in opioid and nonopioid medication utilization, we arbitrarily assigned a coefficient of plus 0.5 to a reported increased medication consumption, and a coefficient of negative 0.5 was assigned to the reported decreased consumption. Similarly, coefficients of plus or minus 1.0 were used for new start or discontinuation of either narcotic or nonnarcotic drugs. Average (coefficient of changes in medications use) per patient was then calculated for narcotics and nonnarcotics separately.

TABLE 2. Summary of ICD-9 Reimbursement Codes in Chronic Pain Management

Description	Code
Medical back problems	722.1, 722.73, 722.83
Cranial and peripheral nerve disorders	250.6, 322.9, 337.1, 337.21, 337.22, 354, 354.1, 354.3, 355.3, 355.4, 355.71
Peripheral vascular disorders	440.21, 440.22
Connective tissue disorders	710.1

ICD-9, International Classification of Diseases, Ninth Edition/Revision.

TABLE 3. Patient Characteristics

Parameter	
Age, yrs (mean ± SD)	46.0 ± 12.5
Range	21–71
Gender, n (%)	
Male	61 (31.1)
Female	135 (68.9)
No. previous surgical procedures (mean)	3.1
Implant duration, years (mean ± SD)	3.1 ± 2.3
Range	0.5–8.9
Primary reason for implant, %	
CRPS I and II	54.0
Back and leg pain	35.0
Critical limb ischemia	4.8
Polyneuropathy	4.8
Other	1.4

SD, standard deviation; CRPS, complex regional pain syndrome.

Cost Identification

The total incidence of surgical and nonsurgical complications associated with SCS/PNS implants was determined. The number of years between implant and the last date of re-

corded visit was adjusted for patients who no longer continued their care at the institution. Based on institutional statistics, an average of 2 physician visits per year was assumed for periodic stimulation parameter adjustment. A cost profile of operative charges was developed from those costs associated with specific diagnosis-related group codes applicable in 2001.[21] These represent the 90-day perioperative period and would, for example, represent the cost of removing a SCS or PNS implant: a mixed cost base depending on the specific reason for its removal. Allowance was also made to include the additional impact that infection with attendant hospitalization would have on the basic surgical costs of removal for malfunction. The total average cost and duration of implantation were calculated in the following manner: total number of all surgeries and maintenance events (ie, trial implants, implants, removals, and complications associated with PNS and SCS) and subsequent physician visits multiplied by the average cost per procedure. For example, the total cost of replacing 52 device generators, at an average cost of US $13,154, would be US $684,008. The costs of each procedure were then added to yield total charges for all patients. These values were divided by the total number of patients included in the survey, which yielded the average charges per patient over the average life of the implant. The net savings per patient was then derived from the difference in costs and savings.

RESULTS

Patient Demographics and Characteristics

Neurostimulation Outcomes Questionnaires were mailed to 222 consecutive patients who received SCS or PNS implants at the Department of Pain Management at the Cleveland Clinic Foundation (CCF) between 1990 and 1998. One hundred twenty-eight patients completed and returned questionnaires; of the 94 patients who did not, 74 were lost to follow-up, 18 chose to not participate in the study, and 2 were deceased.

Medical records from 196 of 222 patients were reviewed for demographics (Table 3). The majority (68.9%) of patients were female. The mean patient age at the time of survey distribution was 46.0 ± 12.5 years (range 21–77 years). Time since device implantation was 3.1 ± 2.3 years (range 0.5–8.9 years). Patients averaged 6.3 years from the first medical visit for the chronic intractable neuropathic pain to device implantation. Indications for neurostimulation included failed back surgery syndrome with chronic axial lower back pain, with leg pain (28.6%) or without leg pain (6.4%); CRPS I and II (54%); critical limb ischemia (4.8%); polyneuropathy and plexopathy (4.8%); mononeuropathy (3.2%); and postherpetic neuralgia (1.6%). The SCS system was implanted in 168 (85.7%) patients, whereas the PNS system was implanted in 20 (10.2%) patients. Both SCS and PNS systems were implanted in 8 (4.1%) patients. The majority (88%) of SCS systems were completely internalized (implanted pulse generator), and 12% were externalized (radiofrequency coupling). A percutaneous SCS trial, if successful, was followed by a surgical implant of a percutaneous electrode and pulse generator in 73.9% of patients and by a laminectomy or 2-stage surgical trial and implant of the pulse generator in 26.1% of patients.

Reimbursement for Neurostimulation Implants

The medical records of 196 patients who were treated with SCS and/or PNS implants were reviewed. The reimbursements associated with SCS/PNS implants are summarized in Table 4. Of the 176 patients undergoing SCS trial, 143 were subsequently implanted in the outpatient setting at an average reimbursement of $19,687 (total cost = $2,815,241). An additional 28 patients received a PNS implant at an average reim-

TABLE 4. Summary of SCS/PNS Reimbursements*

	No. Events	Physician Portion†	Facility Portion†	Total per Patient Cost†	Grand Total
SCS trial, OP	176	420	6,828	7,248	1,275,648
SCS Implant, OP	143	859	18,828	19,687	2,815,241
SCS Implant (2-stage surgical), IP	50	967	23,163	24,130	1,206,500
PNS Implant, IP	28	438	21,512	21,950	614,600
Generator replacement PNS/SCS, OP	52	326	12,828	13,154	684,008
SCS lead revision (replace or reposition), IP/OP	51	430	13,263	13,693	698,343
SCS removal (infection, failure, improvement) OP	21	891	2,928	3,819	80,199
PNS removal, OP	6	345	2,864	3,209	19,254
Follow-up visit after 3 mos past surgery	196	257	207	464	90,944

*Includes reimbursements associated with screening, implantation, complications, hardware failures and maintenance.
†US dollars. Includes facility and supplies. Cost of anesthesiology not included.
SCS, spinal cord stimulation; OP, outpatient; IP, inpatient; PNS, peripheral nerve stimulation.

bursement of $21,950. The procedure with the highest associated reimbursement was the 2-stage inpatient SCS procedure, which averaged $24,130 in 50 patients. There were relatively few complications that led to the removal of the implant; 27 patients (21 SCS; 6 PNS) had their implants removed at a total cost of $99,453. The primary cause of device removal included infection (37.0%); less frequent causes of removal included failure of device (11.1%) and dissatisfaction with the degree of efficacy (7.4%). In our analysis, the total estimated reimbursement for SCS/PNS over the 3.1-year duration of implant was $38,187 per patient (does not include pharmacotherapy or anesthesia fee).

Utilization of Healthcare Resources

Healthcare resource utilization before and after SCS/PNS implantation is summarized in Table 5. Before treatment with SCS/PNS implants, patients extensively used healthcare resources to manage their chronic neuropathic pain. Notably, this patient group underwent multiple surgical procedures, which accounted for a significant portion of costs. Additionally, patients were frequent visitors to physician offices, pain clinics, and emergency departments for nerve blocks and other healthcare services. After treatment with SCS/PNS, patients achieved marked reductions in office and emergency department visits, hospitalizations, and notable reductions in the annualized number of pain-related surgeries (0.4) and nerve blocks (13.2). Although reimbursement data addressing pharmacotherapy consumption were unavailable, patients were also able to reduce their pharmacotherapy consumption for both opioid and nonopioid medications by 0.42 and 0.32 in coefficient of utilization per patient per year, respectively. In addition, over the duration of a patient's intractable pain and duration of device implantation, there was an average annualized decrease in MRI use of 0.4 per year and a decrease in CT scans of 0.2.

The per patient annual cost savings associated with SCS/PNS is $30,221, largely attributed to dramatic reductions in nerve blocks, emergency department visits, and hospitalizations. Over the 3.1 years of average implant time, there was a total cost savings per patient of $93,685. When assessed over the mean follow-up period of 3.1 years, approximately $5,118 of the savings was attributed to a reduction in surgical interventions, and another $2,520 in savings on medical imaging (ie, MRI, CT). In total, these analyses suggest that SCS/PNS is associated with a net annual savings of $17,903.

DISCUSSION

In this era of cost control, healthcare professionals are under increasing pressure to validate the cost effectiveness of various healthcare delivery approaches. When we initiated this study, no literature was available on the potential or actual cost savings associated with the neurostimulation use in the management of intractable chronic pain. Therefore, we set out to determine whether SCS/PNS could materially reduce direct medical costs. Because computerized data on patient utilization of healthcare resources are not currently available in most institutions, many investigators have acquired their data from self-administered patient questionnaires, or alternatively, through patient interviews.[23] Although there may be some concern over the validity of self-reporting, patient recollection is 1 approach to assessing the changes in actual utilization of healthcare resources, such as shifts in analgesic use, injections, physician's office or emergency department visits, surgeries, and diagnostic procedures.[24]

In the present study, we were able to estimate the actual medical costs saved by summing up the changes in utilization

TABLE 5. Utilization of Healthcare Resources and Cost Savings

	Per Patient Per Year					
	Before*	After†	Change	Professional Fee, US $	Facility Fee, US $	Total Cost Savings, US $
Physician office visit	20.6	12.1	−8.5	50	207	2,185
ED visit	3.2	0.7	−2.5	736	828	3,910
Hospitalization	2.9	0.7	−2.3	840	2,484	7,645
Injection (nerve block)	15.7	2.5	−13.2	214	849	14,032
Surgery	3.1	0.9	−0.4	669	3,458	1,651
MRI scan	1.8	0.2	−0.4	677	797	590
CT scan	1.5	0.5	−0.2	316	797	223

Calculation of these numbers was based on the total number of events reported before implant divided by years between first medical visit for pain problem to implant minus total number of events after implant divided by time since implant.
*Before refers to the time interval between the first medical visit for pain problem and device implantation.
†After refers to the time interval since device implantation to the date questionnaire was returned.
ED, emergency department; MRI, magnetic resonance imaging; CT, computed tomography.

of healthcare parameters that were reported by patients following implantation of their neurostimulation devices. Management models were derived from the clinical literature, expert opinion, and published diagnostic and therapy protocols. Costs were obtained from standardized charges and statistical information drawn from national databases.[21,22] Using these data, we found that patients achieved an average net savings of $93,685 over the 3.1-year average implant duration. The average cost of SCS/PNS was $38,187; therefore, cost benefits begin to accrue within approximately 2 years of implantation. Although the facility cost of the anesthesiologist was not included in the analysis, this component is expected to contribute modest costs because Medicare reimbursement for a procedure of approximately 3 hours is typically less than $300 ($17.17/15-minute units). Consequently, the magnitude of adjustment in facility fees for the surgeries commonly used in this study is expected to be limited to approximately 5% to 10%. Additionally, we did not report the potential savings in pharmacotherapy utilization. Other studies have reported annual pharmacy costs of approximately $861 (Canadian dollars) in patients receiving nonsurgical care.[25] Although previous studies have demonstrated cost savings in analgesia use in patients treated with spinal stimulators, the magnitude of savings is not expected to be large.[17,25] Irrespective of these potential shortcomings, our cost effectiveness analysis was comparable to the results reported by Bell et al[17] in patients with Failed Back Surgery Syndrome. In that study, the authors concluded that SCS lowered medical costs and that on the average, SCS therapy paid for itself within 5.5 years for all patients and 2.1 years or less in patients who responded well to SCS therapy.

Several shortcomings in our methodology are apparent. First, these data are based on retrospective analysis without benefit of a control group. Also, perhaps the "natural history" of chronic pain patients who are refractory to all types of interventions, and who have reached the end of various treatment algorithms, may incur fewer direct medical costs. For instance, we may or may not have seen a comparable result in patients who were less aggressively treated. Nevertheless, by comparing healthcare utilization before and after implantation with each patient serving as their own control, we have captured information on longitudinal disease management in a group of patients whose care is otherwise very fragmented and repetitive.

The assessment of savings is entirely based on patients' reports in the Neurostimulation Outcomes Questionnaire. It therefore depends on record bias and changes in status subsequent to implantation, both of which are major potential threats to the validity of this type of study.[24] Unfortunately, CCF, like many healthcare facilities at the time of this investigation, had no automated data available. Most studies on utilization of healthcare resources currently use data obtained from self-administered questionnaires or interviews.[23] To validate our methodology, we conducted a semiquantitative review that entailed a random sample of 12 patients. Medical inpatient and outpatient documents and computerized medical history—both at the Pain Management Center and in a separate hospital-wide computer system that included emergency department visits, numbers of surgeries and diagnostic interventions since 1998—were correlated with the numbers reported by our patients. The changes in medication prescriptions after implantation, emergency department visits, and number of injections and surgeries were found to have been reported by patients with a reasonable degree of accuracy. Any discrepancy between patient reports and documented events might reflect that a tertiary medical center such as CCF accounts for only a portion of their healthcare, the major proportion of which may take place at community hospitals. The ideal cost-benefit analysis would be largely based on third-party payors' actual reimbursement figures. These might include utilization of resources outside the health network and might indirectly help curb repetitive and inappropriate care in this difficult group of patients.

One-third of all patients qualifying for the Neurostimulation Outcomes Questionnaire could not be reached by mail or telephone in 2 separate attempts. A significant proportion of these patients may have had follow-up care at a local pain clinic or had moved one or more times since SCS/PNS implantation. Additionally, several of our patients were currently involved in litigation or compensation disputes and either did not wish to volunteer any pertinent information or were legally advised not to do so. Nevertheless, in a medical chart review for about half of these nonresponders, the distribution of overall outcomes—pain relief, perception of successfulness, utilization of healthcare resources, quality of life, activities of daily living, physiological indices, return to work, and disability payments—appears to be comparable with that of patients who had returned the questionnaire.

Approximately 12% of patients undergoing SCS trial implantation at our institution will not satisfy requirements for permanent implantation. Several of the patients in this study, as a result of lead instability or because of anatomic difficulties during attempted implantation, proceeded to have a surgically placed (laminectomy) SCS system and were included in the study. Approximately 24% of patients indicated that they were no longer using their stimulation devices. Some of these patients were scheduled for surgical implant or device revision for specific problems such as lost stimulation paresthesiae or technical failure (eg, broken lead or battery failure at the time of the survey). A few of these patients reported substantially improved control of their pain symptoms since the implant. A number of patients showed a favorable pattern in medical resource use despite apparent failure with neurostimulation. This may reflect the natural history of their chronic pain problems or may result from different medical management, such as surgery, complimentary medicine, or behavioral treatment, rather than as a consequence of SCS or PNS.

In conclusion, using a cost-benefit analysis and cost-identification analysis of SCS and PNS by means of a patient outcomes questionnaire, we have identified marked savings in direct medical costs 3.1 years after implantation. Although we did not directly compare the efficacy of SCS/PNS with other treatments in a controlled setting, there is a cost savings associated with this modality, which indirectly suggests that the treatment is perhaps more efficacious. Nevertheless, we believe that the results reported in this study supports the use of neurostimulation or combination of neurostimulation and other strategies in the management of patients with chronic neuropathic intractable pain while at the same time reducing overall medical costs.

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TREATMENT OF CHRONIC PAIN WITH SPINAL CORD STIMULATION VERSUS ALTERNATIVE THERAPIES: COST-EFFECTIVENESS ANALYSIS

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OBJECTIVE: There is limited available research measuring the cost-effectiveness of spinal cord stimulation (SCS), compared with best medical treatment/conventional pain therapy (CPT). The purpose of this study was to tabulate the actual costs (in Canadian dollars) for a consecutive series of patients treated with SCS in a constant health care delivery environment and to compare the costs with those for a control group treated in the same controlled environment.

METHODS: We present a consecutive series of 104 patients with failed back syndrome. Within this group, 60 patients underwent SCS electrode implantation, whereas 44 patients were designated as control subjects. We monitored these patients for a 5-year period and tabulated the actual costs incurred in diagnostic imaging, professional fees paid to physicians, implantation (including the costs for hardware), nursing visits for maintenance of the stimulators, physiotherapy, chiropractic treatments, massage therapy, and hospitalization for treatment of breakthrough pain. From these data, the cumulative costs for each group were calculated for a 5-year period. An analysis of Oswestry questionnaire results was also performed, to evaluate the effects of treatment on the quality of life.

RESULTS: The actual mean cumulative cost for SCS therapy for a 5-year period was $29,123/patient, compared with $38,029 for CPT. The cost of treatment for the SCS group was greater than that for the CPT group in the first 2.5 years. The costs of treating patients with SCS became less than those for CPT after that period and remained so during the rest of the follow-up period. In addition, 15% of SCS-treated patients were able to return to employment because of superior pain control and lower drug intake. No patients in the control group were able to return to employment of any kind.

CONCLUSION: SCS is cost-effective in the long term, despite the initial high costs of the implantable devices.

KEY WORDS: Chronic pain, Cost-effectiveness analysis, Spinal cord stimulation

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Chronic benign pain in general, and back pain in particular, has generated interest because of its persuasive nature and the high treatment costs, loss of earnings, reduced productivity, and individual suffering involved. Spinal cord stimulation (SCS) has proven to be an effective therapeutic modality for the treatment of certain chronic pain syndromes (4, 5, 7, 11, 14, 19–21, 24). Our experience with SCS for the treatment of chronic benign pain encompasses two decades (14). Common indications for SCS include failed back syndrome, pain associated with peripheral vascular disease, peripheral neuropathies, multiple sclerosis, and complex regional pain syndrome I (1, 9, 12, 13, 15). Patients who received SCS in our series were all gated through multidisciplinary pain clinics, where traditional modalities of pain relief had failed. Although the literature recognizes that SCS has its place in the treatment of chronic intractable pain, there are few data to measure the cost-effectiveness of SCS in chronic pain therapy. The financial pressures on third-party payers with advances in medical technology have increased the need for physicians to include cost-effectiveness as a parameter in treatment planning.

The purpose of this study was to evaluate the costs of SCS therapy, compared with conventional pain therapy (CPT), for a consecutive series of 104 patients with failed back syndrome. In this group, 60 patients underwent SCS, whereas 44 patients

continued treatment with conservative treatment modalities. To quantify the effects of these treatments on the quality of life, the Oswestry questionnaire (6) was administered at the time of patient enrollment into the study and during the follow-up period.

Our data suggest that the cumulative costs of SCS therapy are bimodal, with an initially high component for 2.5 years because of the requirement for expensive implantable hardware. After that period, the costs of CPT were greater than those of SCS therapy through 5 years. We made no attempt to attribute monetary values to the degree of pain relief, the benefits of a return to employment, improvements in the quality of life, or reductions in workman's compensation benefits, where applicable, because of multiple variable factors and the subjectivity that such calculations would impose. Such considerations would increase the advantages of SCS over CPT.

PATIENTS AND METHODS

Patient Selection

We have a large database that includes data for 350 patients who have undergone SCS in the past 20 years. For this study, we extracted data for consecutive patients with failed back syndrome. One hundred twenty-two patients were included in that category. All patients were initially gated through a multidisciplinary pain clinic, where conservative methods had failed. The patients were then referred for SCS therapy. While these patients were awaiting trial stimulation, 18 patients either moved or refused to participate in the study and thus were lost to follow-up monitoring. Because none of those 18 patients received further treatment of any kind, they did not incur further expense to the system. Therefore, we did not factor in anticipated costs for the purposes of this study.

These exclusions left a working group of 104 patients who were monitored for a minimum of 5 years. The data were derived from chart reviews and follow-up appointments, supplemented with telephone interviews. The patients were then subdivided into two groups, i.e., Group A (with implants, SCS group) and Group B (without implants, CPT/control group). The groups were matched with respect to age, sex, mean number of operations performed before enrollment into the study (3.3 operations), and time away from work since injury (minimum of 1 yr), and all patients were evaluated by the same multidisciplinary pain specialist group.

Group A consisted of 60 patients (57.7%; 28 female patients [47%] and 32 male patients [53%]), with a mean age of 52.3 years. After evaluations and successful trials, these patients underwent permanent SCS electrode implantation, and they continued to achieve more than 50% pain relief throughout the 5-year follow-up period. There were no explantations of the system because of loss of pain control; although four patients exhibited slight decreases in efficacy during the follow-up period, they continued to be quite comfortable and satisfied with the stimulation program.

The control group design was necessarily limited by practical considerations for human experimentation. An ideal control group would be composed of patients who were referred for SCS and responded favorably to trial stimulation but were then randomly assigned to the implant-treated group (surgical treatment, Group A) and a control group (Group B) in which the functioning electrode was removed after trial stimulation. In that event, the patients in the control group would have undergone surgical procedures specifically designed not to benefit the patients, which is an ethically intolerable situation. To maintain consistency in as many parameters as possible, including the use of a surgical procedure, our control group (medical treatment, Group B) was defined as patients who were referred for SCS but did not undergo electrode internalization. Internalization was not performed because those patients did not achieve more than 50% pain relief from their stimulators, despite stimulation-induced paresthesia covering the territory of the pain. The failure to achieve pain control may be attributable to nonspecific reasons. This control group constitutes a reasonable sample for comparisons between long-term surgically treated and conservatively treated patients with similar causes for their pain.

Group B consisted of 44 patients (42.3%; 21 female patients [48%] and 23 male patients [52%]), with a mean age of 51.4 years. This group was treated with conservative/noninterventional therapies, was matched with Group A, and was monitored every 6 months (in a manner similar to that for Group A) during the 5-year study period.

Cost Calculations

The costs tabulated in this study are actual costs based on year 2000 prices, in Canadian dollars. The costs incurred in the treatment of patients who underwent SCS were calculated under the following headings: 1) hardware used in SCS, 2) professional fees, 3) radiological investigations, 4) hospital admissions, 5) drugs, 6) nursing contacts, and 7) electrode or pulse generator replacement during the 5-year follow-up period. The costs of treatment for patients who were monitored with medical treatment were calculated in a similar manner, using the following parameters: 1) physician and other health care professional fees, 2) drugs, 3) radiological investigations (computed tomographic [CT]/magnetic resonance imaging (MRI), myelographic, and x-ray studies), 4) alternative therapies (massage, physiotherapy, and chiropractic treatments), and 5) hospital admissions for treatment of breakthrough pain.

Effects of the Canada Health Act

To non-Canadian readers, the cost calculations presented in this article may seem low, compared with their experience in the United States or western European countries. The lower financial costs are attributable to differences in pricing by the manufacturer of the implantable devices used and tight regulation (by the provincial or federal government) of the fee schedules for various professional organizations. However,

the cost comparisons between SCS and CPT are valid on a relative basis. It is important to note that, in Canada, the health care system is universal, accessible, comprehensive, portable, and publicly funded and is governed by the Canada Health Act, which was enacted in 1984 by the federal government and is administered by each province for its subjects. The Canada Health Act outlines necessary requirements that provincial health care insurance plans must fulfill. Under this act, hospitals are prohibited from adding any premium to the actual cost of any implantable device.

Costs of Implantable Devices

The costs for implantable devices were calculated from the year 2000 price list provided by the manufacturer (Medtronic of Canada, Ltd., Mississauga, ON, Canada), as charged to Canadian hospitals. We used the actual prices charged to hospitals by the manufacturer, because no increases in the prices to patients are permissible under Canadian law. The implantable devices used in SCS treatment consisted of an electrode, pulse generator, and connector cord. The pulse generator needed to be replaced after 3.5 to 4.5 years (the average lifespan of its battery). Some designs are externally powered and do not require periodic battery replacement; however, those devices have poor patient acceptance because of the inconvenience of carrying the transmitter on the belt and the use of antennae, which frequently cause skin rashes and allergic reactions. For our calculations, we observed that the frequency of pulse generator replacement was, on average, once every 4 years. Our study also revealed that the electrode required replacement once every 5 years, on average, because of fracture, migration, or fibrosis. The cost associated with electrode replacement was amortized for a 5-year period, because there was no identifiable average electrode lifespan.

Costs Associated with Iatrogenic Complications

The following iatrogenic complications were observed: 1) superficial infections that resolved with antibiotic treatment, without explantation; 2) infections that required explantation and treatment with antibiotics, followed by reimplantation; and 3) respiratory complications that required antibiotic treatment and prolonged hospital stays. In the first 1 year after implantation, we observed four infections. In two cases, the infections were superficial and resolved with intravenously administered antibiotics. The other two cases required explantation, followed by antibiotic therapy and reimplantation. Eight cases involved minor respiratory complications, such as atelectasis or pneumonia. These were treated with appropriate antibiotics as indicated, in conjunction with respiratory therapy.

Medical Personnel Costs

Physicians and other health care professionals in Canada are paid on a fee-for-service basis. The fee schedules for various professional bodies are controlled by the provincial governments, after negotiation with the professional licensing bodies. The fees paid to the various physicians and surgeons in the study were derived from the year 2000 payment schedule for the Saskatchewan Medical Association.

Nursing and Allied Health Care Professional Costs

The costs of nursing contacts for the maintenance of patients enrolled in the SCS group were derived from the hourly wages paid to the health care workers, as determined by the nursing union contract. Each patient contact was equated to 1 hour of wage. A similar approach was used for social worker involvement. The costs of physiotherapy, chiropractic treatment, massage therapy, and acupuncture were determined on the basis of the fee schedules approved by the respective associations.

Costs of Investigations

The costs of various imaging procedures (CT, MRI, myelographic, and x-ray studies) were provided by the finance department of the Regina Health District.

Hospitalization Costs

The daily hospitalization cost, as approved for the institution at which the study was conducted, was $627. This was the exact amount paid to the hospital by the government of Saskatchewan in the year 2000. No markup is chargeable to patients, according to Canadian law.

Pharmacotherapy Costs

The pharmacotherapy costs that the patients paid for pain management were determined by using the Saskatchewan Health Formulary (*Table 1*). The drugs commonly used by patients in our series included antidepressants, benzodiazepines, opioids, nonsteroidal anti-inflammatory drugs, analgesics, and muscle relaxants. These costs were determined on a monthly basis, allowing a prefixed, government-approved, pharmacy markup schedule (over wholesale prices) and a flat rate for dispensing (*Table 1*), according to the current pharmaceutical standards of practice. In our province, the government approves the wholesale price of each drug, the allowable markup for each drug, and the chargeable dispensing fees.

TABLE 1. Formulae used in the calculation of costs for pharmacotherapy[a]

A. Wholesale cost of a particular medication/mo = wholesale cost of medication/pill × number of pills consumed/patient/d × 30 d/mo

B. Pharmacy markup schedule (over wholesale cost)
$0–6.31, 30% markup
$6.32–15.81, 15% markup
$15.81–200.00, 10% markup

C. Dispensing fee for each drug for 1-mo supply = $7.15

[a] Total cost/mo/medication = Cost A + Cost B + Cost C.

Cumulative Cost Calculations

Group A

The actual cumulative costs were determined via data collection under the following headings (*Tables* 2 and 3): 1) professional costs (medical consultation fees and surgical costs); 2) costs of various imaging investigations; 3) costs of implantable equipment (electrode, pulse generator, and in-line connector); 4) costs of treatment of iatrogenic complications (infections); 5) costs of pharmacotherapy to control breakthrough pain; 6) hospital admission costs for implantation, if needed; 7) SCS maintenance costs, calculated by adding fees associated with physician contacts, nursing contacts, electrode changes because of fracture, malfunction, or shifting (with the associated professional costs and hospital charges for treatment of the pathological condition), and pulse generator changes (with the associated professional costs and hospital charges); and 8) physician contact costs (statistical analysis for our series revealed that patients with functional implants visited a family physician four times/yr and a neurosurgeon twice/yr). After we determined the yearly costs, we extrapolated the cumulative costs for a period of 5 years (*Tables* 2–4).

TABLE 2. Evaluation and implantation cost[a]

	Unit cost ($)	Average unit frequency (d)	Average unit cost ($)	Average cost/ patient ($)
Consultation				
Psychiatrist	108			
Social worker	84			
General practitioner	44			426
Neurosurgeon	57			
Neurologist	85			
Orthopedic surgeon	48			
Investigations				
CT scans	465	1.7	822	
MRI scans	1045	1.1	1184	2390
X-rays	36	5.6	202	
Myelograms	135	1.4	182	
Surgery				
Anesthesia				
Implantation	192			
Internalization	93			
Neurosurgical professional fees				1156
Implantation	593			
Internalization	216			
Assistant surgeon	62			
Pulse generators				
Itrel III	5825			
Itrel II	5675			6110
X-trel	7650			
Electrodes				
Resume	1595			1595
Pisces-Quad	1595			
In-line connector	625			625
Complications				
Explantation	236	2	472	
IV antibiotic treatment	56	2	112	308
Reimplantation	8617	2	17,234	
Respiratory complications	153	4	612	
Antibiotics for superficial infections	14	2	28	
Hospital admission	627	6.9		4326
Total				16,936

[a] CT, computed tomographic; MRI, magnetic resonance imaging; IV, intravenous.

Group B

The actual cumulative costs were determined via data collection under the following headings (*Table 5*): 1) costs of evaluations by various health care professionals, including family physicians, orthopedic surgeons, psychiatrists, social workers, neurologists, and neurosurgeons; 2) imaging costs (CT, MRI, x-ray, and myelographic studies) required initially and during episodes of pain flare-up (in our series, it was observed that patients required one CT study and one MRI study every 2 yr); 3) pharmacotherapy costs, calculated as outlined for Group A; 4) costs of alternative therapies (physiotherapy, chiropractic treatments, massage therapy, and acupuncture); and 5) costs of intermittent hospitalization for treatment of acute breakthrough pain (in this series we observed that patients experiencing breakthrough pain required an average of 3 d of hospitalization/yr). It should be noted that surgical costs, including the costs of hardware for trial stimulation and hospital charges for that time, were not included for Group B.

Evaluation of Quality of Life and Patient Satisfaction

To determine the effects of SCS treatment on the quality of life and function, we administered the Oswestry disability questionnaire (6) at the time of enrollment into the study and every 1 year during the follow-up period. The results were then averaged for a 5-year period. With a separate questionnaire, patients who underwent SCS were questioned regarding their satisfaction with the treatment, whether they would undergo a repeat procedure for the same degree of benefit, and whether they would recommend this procedure to their friends and relatives with similar pain problems.

RESULTS

Group A

Sixty patients were included in Group A. Calculations of the average initial costs of implantation for the patients who received permanent SCS implants are summarized in *Table* 2.

TABLE 3. Costs of spinal cord stimulation maintenance

Description	Unit cost ($)	Unit (frequency)	Cost ($)	5-yr cost ($)
Physician contacts				
Family physician	44	4 visits/yr	176	
Neurosurgeon	57	2 visits/yr	114	
Total			290	1450
Nursing contacts for stimulation parameter optimization and counseling	30	3.1 visits/yr	92	460
Pharmacotherapy for pain flare-ups	302			1510
Electrode change[a]	1595	1	1595	1595
Professional costs for electrode change[a]				
Anesthesia	93			
Neurosurgeon	275			
Hospital charge	75			
Total	443			443
Pulse generator replacement[b]	6005	1		6005
Professional fees for pulse generator change[b]				
Anesthesia	284			
General practitioner consultation	44			
Neurosurgeon consultation	57			
Neurosurgeon	202			
Assistant surgeon	62			
Hospital charge	75			
Total	724			724
Total (5-yr cost)				12,187

[a] Once in every 5-year period.
[b] Once in every 4-year period.

TABLE 4. Costs of treating a patient with chronic pain with stimulation for 5 years

Data	Costs ($)
Table 2	16,936
Table 3	12,187
Total (*Table 2* + *Table 3*)	29,123

The types of pulse generators used in this study included Itrel II, Itrel III, and X-trel (Medtronic, Inc., Minneapolis, MN). Thirty-nine patients (65%) received Itrel II pulse generators, 14 (23%) received Itrel III pulse generators, and 7 (12%) received X-trel pulse generators. The average pulse generator cost was $6110. The electrodes used in this series were either Resume or Pisces-Quad electrodes (Medtronic, Inc.), with an average price of $1595. The average cost for the in-line connectors was $625. The initial imaging costs (before implantation) for x-rays, myelograms without CT scans, CT scans, and MRI scans of the lumbar spine were $202, $182, $822, and $1184, respectively, totaling $2390. Professional costs, which included costs for initial assessments by a primary care physician and consultation services rendered by an orthopedic surgeon, psychiatrist, social worker, neurologist, and neurosurgeon, totaled $426. The costs of surgery and anesthesia for implantation were $1156 for each implantation procedure. The average cost for treatment of iatrogenic complications was $308. The hospital charges during the study period were $627/d, with an average hospital stay of 6.9 d/patient, totaling $4326. These costs totaled $16,936/patient in the year of implantation (*Table 2*).

Maintenance costs included costs for follow-up monitoring by a family physician, a neurosurgeon, and a neuromodulation nurse and the costs of medications used during flare-up periods (*Table 3*). Patients with functional implants visited their family physicians four times/yr and a neurosurgeon twice/yr, at a total cost of $290/yr. Neuromodulation nursing contact costs for implant maintenance (optimization of stimulator parameters) were $92/yr/patient; an average of 3.1 contacts/yr were required. The cost of medications for the treatment of breakthrough pain was $302/yr. Our records

TABLE 5. Annual medical resource use by patients who have undergone nonsurgical chronic care[a]

Therapy description	Unit cost ($)	Average unit (frequency)	Cost/yr ($)	5-yr cost ($)
Physician visits (24 visits/yr with family physician)	22	24	528	2640
Specialist consultation				
1 visit with neurologist	85	1	85	425
1 visit with neurosurgeon	57	1	57	285
1 visit with orthopedic surgeon	48	1	48	240
1 visit with psychiatrist/psychologist	108	1	108	540
Social worker	21	4 h	84	420
Hospitalization for breakthrough pain	627	3 d	1881	9405
Medications (antidepressants, anti-inflammatory agents, benzodiazepines, muscle relaxants, opioids)[b]	861		861	4305
Alternative therapies				
Physiotherapy	30	57.6	1736	8680
Chiropractic treatment	22	17.2	373	1865
Massage therapy	40	10.1	404	2020
Acupuncture	35	10.6	371	1855
Total for alternative therapies			2884	14,420
Total maintenance cost (Cost A + Cost B + Cost C + Cost D + Cost E)				6536
Initial diagnostic procedures[c]				
CT scans, lumbar spine	465	1.8	825	825
MRI scans, lumbar spine	1045	1.0	1071	1071
X-rays, lumbar spine	36	6.8	244	244
Myelograms	135	1.4	189	189
Total for diagnostic procedures			2329	2329
Total			8865	35,009
Diagnostic procedures precipitated by flare-ups during study, CT and MRI scans, lumbar spine[d]	1510	2	3020	3020
Total (5-yr)				38,029

[a] CT, computed tomographic; MRI, magnetic resonance imaging.
[b] Derived from chart review.
[c] For establishing diagnosis and entry into the study.
[d] Performed once every 2 years.

revealed that SCS patients required, on average, one electrode change during the 5-year study period (precipitated by fracture, shifting, or nonfunction); the associated costs of surgery for replacement were $2038 (cost of the electrode [$1595] + professional costs [$368] + hospital costs [$75]). The pulse generator also needed to be replaced an average of once every 4 years, at a cost of $6729, because of battery power depletion.

To determine the cumulative costs, we projected these calculations for a 5-year period by determining the following average costs per patient per year (*Tables* 2 and 3): Cost a, costs of the initial evaluation ($426) and investigations ($2390); Cost b, cost of implantation ($13,812; hardware costs, $8330; surgical fees, $1156; hospitalization costs, $4326); Cost c, cost of treatment of iatrogenic complications ($308); Cost d, SCS maintenance cost ($684; physician, $290; nursing contacts, $92; drugs, $302); Cost e, cost of electrode replacement (once every 5 yr) ($2038; for purposes of calculation, this was amortized for a 5-yr period at $408/yr); Cost f, cost of pulse generator replacement (once every 4 yr) ($6729; pulse generator, $6005; surgical fees, $649; hospital costs, $75). Therefore, the cumulative costs were as follows (*Table 6*): Year 1, Cost a + Cost b + Cost c + amortized Cost d; Year 2, Year 1 cost + Cost c + amortized Cost d; Year 3, Year 2 cost + Cost c + amortized Cost d; Year 4, Year 3 cost + Cost c + amortized Costs d + e;

TABLE 6. Actual annual costs of spinal cord stimulation and conventional pain therapy for 5 years[a]

Year	Actual costs ($)		Cumulative costs ($)	
	SCS	CPT	SCS	CPT
1	18,028	8865	18,013	8865
2	1092	7291	19,120	16,156
3	1092	7291	20,212	23,447
4	7819	7291	28,013	38,738
5	1092	7291	29,123	38,029
Total	29,123	38,029		
Average	5825	7606		

[a] SCS, spinal cord stimulation; CPT, conventional pain therapy.

Year 5, Year 4 cost + Cost c + amortized Cost d. At the end of a 5-year period, the average cumulative cost for this group was $29,123.

During the 5-year study period, none of these patients underwent lumbar spine surgery. Therefore, no extra costs were attributable to such procedures.

Group B

The control group consisted of 44 patients. This group required a greater number of physician visits per year for assessments, as well as to obtain prescriptions for pharmacotherapy or referrals to allied health care professionals. The average number of family physician visits was 24/patient/yr, with an average yearly cost of $528. In addition, each patient sought consultations with various specialists (a neurosurgeon, an orthopedic surgeon, a neurologist, a psychiatrist/psychologist, and a social worker) an average of five times/yr, with a cost of $910/yr. On average, each patient initially required 1.8 CT scans, 1.0 MRI scan, 6.8 x-rays of the lumbar spine, and 1.4 myelograms. Therefore, the average initial imaging costs for this group were $2329. In addition, during the follow-up period, each patient required CT/MRI studies once every 2 years, on average, with a cost of $1510. This group also required hospitalization an average of 3 d/yr, because of acute pain exacerbations, at a cost of $1881. The cost of pharmacotherapy for pain averaged $861/yr (*Table 5*). The average numbers of visits to physiotherapists, chiropractors, massage therapists, and acupuncturists were 57.6, 17.2, 10.1, and 10.6 visits/yr, respectively, yielding a total cost of $2884/patient/yr.

To determine the cumulative costs, we projected these calculations for a 5-year period by determining the following average costs per patient per year (*Table 5*): Cost a, cost of investigations ($2329); Cost b, cost of maintenance (total, $6536; pharmacotherapy, $861; physician contacts, $910; alternative therapies, $2884; hospitalization for treatment of breakthrough pain, $1881); Cost c, cost of secondary investigations every 2 years (costs of CT and MRI scans, $1510 × 2 = $3020, amortized for a 4-yr period as $755/yr, allocated to the second, third, fourth, and fifth years of the follow-up period). Therefore, the cumulative costs per patient for Group B were as follows (*Table 6*): Year 1, Cost a + Cost b; Year 2, Year 1 cost + Cost b + amortized Cost c; Year 3, Year 2 cost + Cost b + amortized Cost c; Year 4, Year 3 cost + Cost b + amortized Cost c; Year 5, Year 4 cost + Cost b + amortized Cost c. At the end of a 5-year period, the cumulative costs for this group were $38,029/patient.

Figure 1 demonstrates that the costs of SCS therapy are greater than those of CPT in the first 2.5 years, because of the initial high costs of the implantable devices. After that period, SCS treatment becomes economically favorable for patients who respond positively to SCS. Although the costs of pulse generator replacement in the fourth year tend to bring the two curves closer, CPT remains relatively more expensive. With projection of these data for a 10-year period, these savings are magnified (*Fig. 2*).

Quality of Life Considerations

Although the cost of therapy may dictate which methods are used for the treatment of chronic pain, patient quality of life is equally important, if not more important. Patient functioning and quality of life were measured by using the Oswestry disability questionnaire (6). The questionnaire indicated a 27% improvement in quality of life for the SCS group, compared with 12% improvement for the control group.

For assessment of patient satisfaction with SCS, an additional questionnaire was used. The responses were graded into three groups, i.e., very satisfied, satisfied, and unsure. Thirty-six patients (60%) reported being very satisfied, 17 patients (28%) reported being satisfied, and 7 patients (12%) were unsure. Because SCS was the only modality that had given the very satisfied and satisfied groups comfort and allowed reductions of drug usage, the patients noted that they

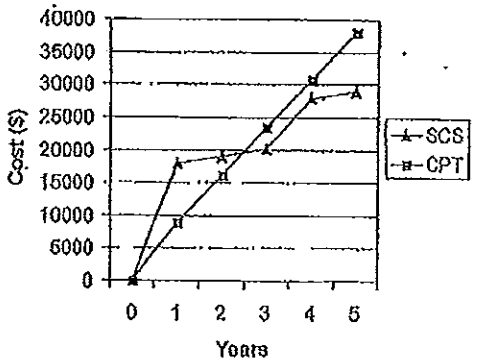

FIGURE 1. *Graph illustrating the cumulative costs of SCS versus CPT for a 5-year period. The 2.5-year payoff period should be noted.*

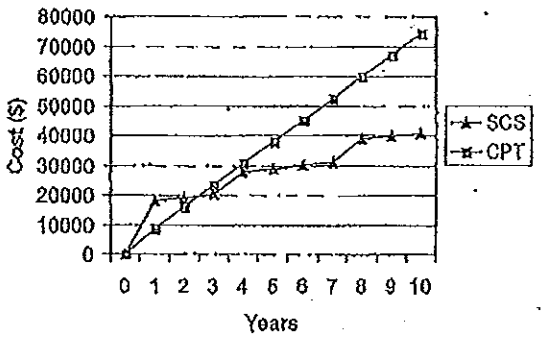

FIGURE 2. *Graph illustrating the cumulative costs of SCS versus CPT projected for a 10-year period.*

would recommend this procedure to relatives or friends with similar pain problems.

A benefit of SCS treatment in addition to the cost savings was that nine patients (15%) in Group A were able to return to some form of gainful employment, compared with none in Group B. Drug intake was also reduced with SCS. Preoperatively, the average cost for drug therapy for pain was $78/mo (this cost was calculated from our patient records before enrollment and is not presented in the tables); postoperatively, the cost decreased to $25/mo. The average pharmacotherapy cost for the control group was higher, i.e., $861/yr ($72/mo).

Statistical Analyses

The actual yearly costs for SCS and CPT for the 5-year period are summarized in *Table 6* and *Figure 3*, which indicate that the average yearly costs for SCS are less than the mean yearly costs for CPT. In an effort to provide realistic costs to hospital administrators for budgeting, we added a net present value of 5% (inflation factor) to the actual costs; these adjusted costs are presented in *Table 7*. Once again, the mean CPT costs are much higher than the mean SCS costs.

We observed that, in *Tables 6* and *7*, the Year 1 cost for SCS therapy ($18,028) is much higher than the costs for the remaining years, particularly Years 2, 3, and 5. This observation may affect analysis of the data and may represent an outlying point in the data set. To provide a reasonable analysis, we redistributed some of the cost from Year 1 to Years 2, 3, and 5. *Table 8* and *Figure 4* present the adjusted costs. We transferred $9000 from Year 1 and added $3000 to each of Years 2, 3, and 5. Importantly, this transfer had no effect on the total or mean costs. It can be observed in *Tables 7* and *8* that the mean yearly costs remained the same, at $6170.32. Therefore, we used the data in *Table 8* for further analysis.

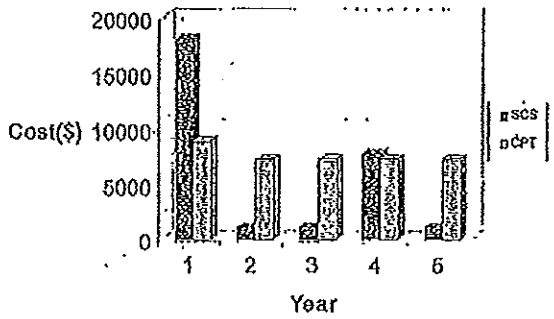

FIGURE 3. *Bar graph illustrating the yearly noncumulative costs of SCS versus CPT for a 5-year period.*

TABLE 7. Inflation-adjusted annual costs of spinal cord stimulation and conventional pain therapy for 5 years (including 5% inflation)[a]

Year	SCS cost ($)	CPT cost ($)
1	18,028.00	8865.00
2	1147.99	7664.81
3	1206.88	8057.80
4	9134.94	8470.93
5	1333.77	8905.24
Total	30,851.58	41,963.78
Average	6170.32	8393.00

[a] SCS, spinal cord stimulation; CPT, conventional pain therapy.

We claim that the mean yearly cost of CPT is higher than the mean yearly cost of SCS. A statistical hypothesis-testing procedure was used to examine this conjecture. In this case, the null hypothesis (H_o) was that the average costs for the two procedures were the same. The research or alternative hypothesis (H_a) was that the mean annual SCS costs were less than the CPT costs. In other words, the null and alternative hypoth-

TABLE 8. Redistributed adjusted annual costs of spinal cord stimulation and conventional pain therapy for 5 years (including 5% inflation)[a]

Year	SCS cost ($)	CPT cost ($)
1	9028.00	8865.00
2	4147.99	7664.81
3	4206.88	8057.80
4	9134.94	8470.93
5	4333.77	8905.24
Total	30,851.58	41,963.78
Average	6170.32	8393.00

[a] SCS, spinal cord stimulation; CPT, conventional pain therapy.

eses are as follows: H_0, there is no difference between the mean costs of the two treatment modalities; H_a, the mean cost of SCS is less than the mean cost of CPT.

The hypothesis test for comparing two population means was investigated with the pooled, two-sample, Student's *t* test. First, we assumed that the population variances were equal. The analysis was performed by using Minitab statistical software (Minitab, Inc., State College, PA), which formulated a *P* value of 0.04. This provided evidence of a significant difference between the average treatment costs for SCS and CPT procedures. It should be noted that the pooled *t* procedures assumed that the population variances were homogeneous. We also performed analysis with unequal population variances; in that situation, the *P* value was 0.58, and thus we reject the null hypothesis of equality of the mean costs at a 5.8% level of significance. In both cases, we reject the null hypothesis. There is sufficient evidence to conclude that the mean yearly cost of SCS is less than the mean yearly cost of CPT. SCS is thus cost-effective, compared with CPT, for the 5-year period. From *Tables 6* and *8*, it can be safely extrapolated that the mean treatment cost for SCS will continue to be significantly smaller than the average treatment cost for CPT as the number of years increases.

Sensitivity Analysis

In this study, we tabulated data from actual patient files, for patients monitored within a constant delivery environment. There are three possible variables that must be considered, i.e., 1) the clinical efficacy rate for SCS, 2) the complication rate associated with SCS, and 3) the lifespans of the pulse generator battery and the electrode.

These variables are less applicable in our case than in other published studies, in which theoretical models of medical resource utilization were used. The clinical efficacy rate has remained stable for the past 10 years but may improve in the future, with the development of more effective patient screening. In our study, no operative procedures were required, except for those related to hardware complications. This incidence has remained constant in all published studies in the past decade, leaving only two variables that may affect costs in the foreseeable future, namely the lifespan of the electrode and the battery life of the pulse generator. The manufacturers are actively pursing improvement of these items. If the manufacturers were to improve the function of these two components by 25% in the future, the payoff period would decrease from 2.5 years to 2.3 years.

DISCUSSION

Shealy et al. (22, 23) were the first to advocate the application of electrical current to the spinal cord to relieve pain. The physiological mechanism by which SCS relieves pain is partially explained by the gate theory proposed by Melzack and Wall (18). In early years, many patients with chronic pain underwent SCS; however, because the selection criteria were poorly defined, the results were far from satisfactory (7). In

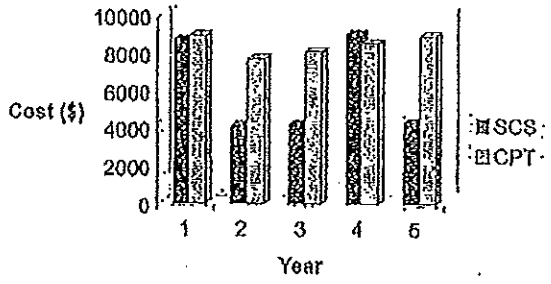

FIGURE 4. Bar graph illustrating the redistributed adjusted costs of SCS versus CPT for a 5-year period, including 5% inflation.

subsequent years, indications were clarified by the work of Lazorthes et al. (16), Winkelmuller (25), Gybels et al. (8), Kim et al. (10), North et al. (20, 21), Kumar et al. (14), Meglio et al. (17), and Barolat et al. (1), and SCS has become an important mode of treatment for failed back syndrome. We attempted to match the two groups with respect to the cause of their pain as much as possible. However, Group B could have a slightly higher proportion of patients with nociceptive pain and Group A patients with lumbosacral rhizopathy. With the increasing costs of medical technology, it is necessary for physicians to provide evidence that SCS is a cost-effective method of treatment, compared with nonsurgical therapies.

To date, there have been only two published studies (2, 3) on the cost-effectiveness of SCS, to our knowledge. Bell et al. (3) demonstrated that, among patients who responded favorably to SCS, the estimated payoff period was 2.1 years. However, in that study, Bell et al. (3) developed theoretical models of medical resource utilization for the two groups of patients (SCS and CPT). Their cost calculations were based on the anticipated use of resources, as determined from clinical literature, retrospective data sets, expert opinions, and published diagnostic and therapeutic protocols. The drawback of that study was that all calculations were based on presumptions, rather than actual recorded costs for the treatment of the two groups. Bel and Bauer (2) monitored 14 patients for the relatively short period of 2 years and concluded that the treatment of chronic pain with SCS was cost-effective, compared with conventional therapy, because the cost of electrode implantation was quickly compensated for by a drastic reduction in drug utilization and increased reentry into the workforce after surgery. That study was limited because of the small number of patients and the short follow-up period, and it failed to provide data for calculation of the recovery period for the high costs of implantable devices used in SCS treatment, compared with CPT.

We designed our study to allow monitoring of a large number of patients in the two groups (SCS and CPT) for a 5-year period and to address some of the flaws in those earlier reports. We recorded the actual costs incurred in the treatment of both groups of patients, increasing the validity of our results. The absolute derived costs may not be directly com-

parable to those encountered and may be lower than those in the United States or Europe. This difference is a consequence of the nature of the medical delivery system in Canada and differences in pricing by the manufacturer in different countries, which limit absolute costs. Because the same economic scale was applied to the various factors that modulate therapy for both of our study groups, our conclusions remain valid on a relative basis.

The cumulative cost for the SCS group for the 5-year period was $29,123/patient (*Table 4*), compared with the control group figure of $38,029/patient (*Table 5*). The higher costs for the non-surgically treated group are attributable to the patients' greater utilization of health care resources for drug therapy, rehabilitation services, and other therapies for pain control (*Table 5*). *Figure 1* indicates that the costs of CPT exceed those of SCS, on a monthly basis, at 2.5 years. In the SCS group, costs are higher in the first 2 years because of the high costs of the implantable devices. After 2.5 years, the costs of primary treatment with SCS become less than those for the control group. This cost benefit is maintained throughout therapy, despite the periodic increases in expenses attributable to the costs associated with hardware manipulation and replacement of the pulse generator (because of depletion of its battery power) (*Fig. 1*).

Our analysis indicates that additional cost savings could result from improvements in the effectiveness of SCS therapy. These improvements might be achieved via more effective patient selection criteria and technological advances in the equipment used. The manufacturers need to focus on methods to improve the longevity of the pulse generator and the durability of the electrode.

CONCLUSIONS

Patients with chronic pain secondary to failed back syndrome who respond to SCS therapy can achieve significant cost savings, compared with a control group. Additional benefits may include an increased rate of work rehabilitation, increased pain control, and a better quality of life. A coordinated approach to the treatment of this disabling ailment can result in better utilization of scarce health care funds.

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COMMENTS

Kumar et al. presented two groups of patients treated by spinal cord stimulation (SCS) and conventional chronic pain therapy (CPT), respectively. They compare the cost-effectiveness of both treatments. In the age of science and technology, these types of cooperative studies are very important in evaluating the real value of surgical methods, which usually seem very expensive. In the presented series, SCS is

shown as not only an effective method but also a cost-effective treatment in comparison with CPT. The most important benefit of SCS was that 15% of the patients went back to work after treatment. Improvement in quality of life was 27% in this group, as compared with 12% in the control group, in which no patient returned to work. Drug intake was also reduced in the SCS group, which is the most important finding of this study. It must be kept in mind that the results of this study reflect the skills of an experienced medical team; another, less experienced group would not necessarily achieve the same results.

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Kumar et al. of the University of Saskatchewan present a study of the cost-effectiveness of SCS as compared with CPT. Sixty patients underwent SCS, and 44 patients in whom a trial of SCS had failed were the controls. These patients were followed for a 5-year period, and actual costs incurred for diagnostic imaging; professional fees paid to physicians; implantation costs, including hardware; nursing visits for the maintenance of the stimulators; physiotherapy; chiropractic; massage therapy, and hospitalization costs for breakthrough pain, were all calculated. In addition, the authors analyzed outcomes based on the Oswestry questionnaire (2) to estimate the effect of treatment on quality of life. On the basis of this analysis, Kumar et al. conclude that the cumulative mean cost of SCS therapy during a 5-year period was $29,122 per patient, as compared with $38,029 per patient for CPT. Extrapolating the cost savings for an additional 5 years on the basis of these data, the authors predict that the cost savings would be even greater.

A number of aspects of this study merit comment. First, the cost of Canadian health care in comparison with that of the United States is a relative bargain in that fees and profits are statutorily limited. Even taking into account the relative inflation of the Canadian dollar in comparison with the U.S. dollar, I think that the actual dollar savings in the United States might be even greater than the savings projected in this study. Nevertheless, the cost analysis is performed within a system that is quite scrupulous about cost accounting.

This type of study is difficult to conduct in any environment. One can certainly quibble about the nature of the "control group." The study was not performed in a group of patients who would otherwise have gone forward with SCS on the basis of a successful trial, which would constitute the authors' "ideal" study, in which patients would be randomized to either SCS or CPT. As the authors point out, this type of randomized study would present some ethical problems. Whether these difficulties can be surmounted in a future study remains to be seen. Nevertheless, the control group (Group B) in this study represents a group in whom an SCS trial had failed and, for that reason, may represent a more difficult category of patient. Potentially, Group B's treatment would seem more expensive than that of the patients who underwent SCS (Group A), regardless of the therapy implemented.

Perhaps most striking is the similarity of the results of this study to those reported by Bell et al. (1). That study also found that the financial breakeven point for SCS was approximately 2 years, as compared with more conservative management. It also found that at 5 years, SCS had a distinct cost-effectiveness advantage over nonsurgical management. The difference between these two studies is that the analysis of Bell et al. was based in part on cost projections, whereas Kumar et al.'s data represent actual costs. That the results of these two studies, which were performed in two different countries under different circumstances, are in such close agreement suggests to me that there is an important principle at work: namely, that SCS does result in health care system cost savings that are realized only after several years. It may well be that a more rigorous Class I outcome study of SCS in comparison with conservative management will be performed. Until that time, this study by Kumar et al. should be considered the benchmark work.

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TREATMENT OF CHRONIC PAIN WITH SPINAL CORD STIMULATION VERSUS ALTERNATIVE THERAPIES: COST-EFFECTIVENESS ANALYSIS

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OBJECTIVE: There is limited available research measuring the cost-effectiveness of spinal cord stimulation (SCS), compared with best medical treatment/conventional pain therapy (CPT). The purpose of this study was to tabulate the actual costs (in Canadian dollars) for a consecutive series of patients treated with SCS in a constant health care delivery environment and to compare the costs with those for a control group treated in the same controlled environment.

METHODS: We present a consecutive series of 104 patients with failed back syndrome. Within this group, 60 patients underwent SCS electrode implantation, whereas 44 patients were designated as control subjects. We monitored these patients for a 5-year period and tabulated the actual costs incurred in diagnostic imaging, professional fees paid to physicians, implantation (including the costs for hardware), nursing visits for maintenance of the stimulators, physiotherapy, chiropractic treatments, massage therapy, and hospitalization for treatment of breakthrough pain. From these data, the cumulative costs for each group were calculated for a 5-year period. An analysis of Oswestry questionnaire results was also performed, to evaluate the effects of treatment on the quality of life.

RESULTS: The actual mean cumulative cost for SCS therapy for a 5-year period was $29,123/patient, compared with $38,029 for CPT. The cost of treatment for the SCS group was greater than that for the CPT group in the first 2.5 years. The costs of treating patients with SCS became less than those for CPT after that period and remained so during the rest of the follow-up period. In addition, 15% of SCS-treated patients were able to return to employment, because of superior pain control and lower drug intake. No patients in the control group were able to return to employment of any kind.

CONCLUSION: SCS is cost-effective in the long term, despite the initial high costs of the implantable devices.

KEY WORDS: Chronic pain, Cost-effectiveness analysis, Spinal cord stimulation

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Chronic benign pain in general, and back pain in particular, has generated interest because of its persuasive nature and the high treatment costs, loss of earnings, reduced productivity, and individual suffering involved. Spinal cord stimulation (SCS) has proven to be an effective therapeutic modality for the treatment of certain chronic pain syndromes (4, 5, 7, 11, 14, 19–21, 24). Our experience with SCS for the treatment of chronic benign pain encompasses two decades (14). Common indications for SCS include failed back syndrome, pain associated with peripheral vascular disease, peripheral neuropathies, multiple sclerosis, and complex regional pain syndrome I (1, 9, 12, 13, 15). Patients who received SCS in our series were all gated through multidisciplinary pain clinics, where traditional modalities of pain relief had failed. Although the literature recognizes that SCS has its place in the treatment of chronic intractable pain, there are few data to measure the cost-effectiveness of SCS in chronic pain therapy. The financial pressures on third-party payers with advances in medical technology have increased the need for physicians to include cost-effectiveness as a parameter in treatment planning.

The purpose of this study was to evaluate the costs of SCS therapy, compared with conventional pain therapy (CPT), for a consecutive series of 104 patients with failed back syndrome. In this group, 60 patients underwent SCS, whereas 44 patients